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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INDUSTRIENS PENSIONSFORSIKRING A/S, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

BECTON, DICKINSON AND COMPANY, VINCENT A. FORLENZA, THOMAS E. POLEN, and CHRISTOPHER R. REIDY,

Defendants.

Case No. 2:20-cv-02155-SRC-CLW

Hon. Stanley R. Chesler
District Judge

Hon. Cathy L. Waldor
Magistrate Judge

AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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Lead Plaintiff Industriens Pensionsforsikring A/S ("Industriens" or "Plaintiff"), by and through its undersigned counsel, brings this action individually and on behalf of all others similarly situated who purchased or otherwise acquired the common stock of Becton, Dickinson and Company ("BD" or the "Company") between November 5, 2019 and February 5, 2020, both dates inclusive (the "Class Period"), and were injured thereby (the "Class"). This action is brought against defendants BD and its current and former executive officers, Vincent A. Forlenza, Thomas E. Polen, and Christopher R. Reidy ("Forlenza," "Polen," and "Reidy," collectively, the "Individual Defendants" and with BD, "Defendants").

Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Plaintiff's information and belief is based upon, among other things, the ongoing investigation that Court-appointed Lead Counsel is conducting under Plaintiff's supervision. This investigation includes, but is not limited to, reviewing and analyzing: (i) documents that BD filed with the U.S. Securities and Exchange Commission (the "SEC"); (ii) securities analysts' reports about BD; (iii) transcripts of BD investor conference calls; (iv) BD press releases and presentations; (v) press and media reports, including online news sources; (vi) public material obtained in connection with the continuing investigations discussed here; as well as (vii) interviews of former employees of or consultants to BD ("Former Employees" or "FEs").[1] Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

[1] For ease of readability while preserving their anonymity, the Complaint uses the terms "he" and "his" in connection with all of the Former Employees.

I. INTRODUCTION

1. This securities class action arises from Defendants' materially false or misleading statements concerning a critical question confronting BD in late 2019 and early 2020: Could the Company deliver the revenue from a key product—the Alaris infusion pump system ("Alaris")—that underpinned BD's fiscal year 2020 ("FY20") financial guidance?

2. Again and again during the Class Period, Defendants' answer to this question was a clear "yes." But these representations were false or misleading, in violation of the securities laws. They materially misrepresented and downplayed the nature, extent, and revenue impact of extensive, undisclosed product issues, compliance violations, and ongoing scrutiny by the U.S. Food and Drug Administration ("FDA") regarding Alaris.

3. Given Defendants' consistent representations during the Class Period, investors were stunned on February 6, 2020 when BD disclosed that ***Alaris sales would halt for multiple quarters*** after extensive discussions with the FDA concerning Alaris compliance and device deficiencies, and, as a direct result, slashed BD's guidance for FY20 by ***$400 million***. In response to this startling disclosure, BD's stock price plummeted ***$33.74*** (nearly ***12%***), wiping out roughly ***ten billion dollars of shareholder equity*** in a single day. This action seeks to recover those losses.

4. BD's Alaris is a software-based medical device that delivers medication or other fluids to patients intravenously. For years, infusion pumps have been subject to substantial FDA regulation and oversight, both because a poorly designed or malfunctioning infusion pump can have severe, potentially deadly consequences and because in recent decades the infusion pump industry has had a poor safety and compliance record. Under governing regulations, manufacturers like BD must seek approval for infusion pump changes that could significantly affect device safety or effectiveness through the FDA's Premarket Notification 510(k) program.

5. Alaris has been a primary revenue driver for BD's largest business segment and BD as a whole since the Company acquired Alaris in 2015. The Individual Defendants, as senior executives of a global medical device manufacturer, knew that a failure to fully comply with FDA regulations governing Alaris jeopardized their ability to continue selling one of BD's biggest cash cows.

6. Against this backdrop, in their Class Period misrepresentations Defendants downplayed, minimized and spun pervasive product and compliance issues that were impacting BD's ability to earn revenues from Alaris in FY20. In particular, Defendants assured the market that after resolving to the FDA's satisfaction technical issues which had temporarily delayed Alaris sales, Alaris was poised to anchor BD's impressive guided FY20 revenue growth.

7. At the start of the Class Period, during the Company's November 5, 2019 quarterly earnings call, Defendants announced BD's FY20 guidance ("FY20 Guidance"). The FY20 Guidance included revenue growth of 5% to 5.5%, weighted toward the last three quarters of the fiscal year. This weighting, Defendants said, resulted from a temporary delay in Alaris shipments to allow for software "upgrades" being completed in the first quarter of FY20.

8. Defendants portrayed the issue as limited and short-term, assuring investors that it would not reduce Alaris sales in FY20, but just "***move the timing of some sales from Q1 to the balance of the fiscal year***."[2] They described discussions with the FDA as focused merely on "the timing of implementation of these upgrades" and whether to "bundl[e] them with a new software version." And Defendant Polen extolled Alaris's growing market share, confirming "***we see no slowdown in that momentum***" and assuring investors that Alaris sales in the final three quarters of FY20 would drive BD to meet its FY20 Guidance.

[2] Throughout the Complaint, all emphasis and alterations are added unless otherwise noted.

9. Investment analysts accepted Defendants' account without reservation. That same day, J.P.Morgan identified the "delayed shipments" of Alaris "that were pushed out to F2Q from F1Q" as "a timing issue rather than a read-through to underlying demand," and described BD as "well positioned to post another year of share gains" in FY20. Wells Fargo likewise reported that the "timing of Alaris pump software upgraded in the US will push sales into FQ2-FQ4."

10. Defendants' subsequent Class Period statements to investors echoed the same refrain. At the Evercore HealthCONx Conference on December 4, 2019, Defendant Reidy boasted BD had gained "200 points" of infusion pump market share in 2019, "and we see that continuing." In response to an Alaris-related question about "revenue deferral" for infusion pumps, Reidy again downplayed the matter as one limited to the front end of FY20, assuring, "***[t]hat's a timing issue. First half issue***." Defendants then reaffirmed BD's FY20 Guidance.

11. On January 14, 2020 an analyst at the JPMorgan Healthcare Conference asked for comment on Alaris "pump shipments" and the Company's previous statements that it was awaiting "guidance from the FDA" relating to the device. Defendant Polen immediately asserted BD had "[f]ully resumed shipping in the first quarter" and the Alaris situation with the FDA had played out "***[e]xactly as expected***." Again, Defendants reaffirmed the FY20 Guidance. Two weeks later, on January 28, 2020, at BD's Annual Shareholders Meeting, Defendant Forlenza once more reaffirmed the FY20 Guidance and assured shareholders: "***[W]e are on track for the full year***."

12. The message to investors was clear: the FDA is satisfied; Alaris is once more shipping and growing market share; issue resolved. Contemporaneous analyst commentary confirms the message was received. On February 3, 2020 Cowen remarked in a research report that BD management had "publicly revealed that ***discussions with the FDA were completed*** and

[that] Alaris U.S. shipments [had] ***returned in full during F1Q***," and concluded that these factors "bode[] well for the set up relative to expectations and the guidance range."

13. Unbeknownst to investors, Defendants' statements regarding Alaris and related FY20 revenues were, at best, materially misleading half-truths. First-hand accounts by Former Employees with responsibilities directly related to Alaris confirm that, by the start of the Class Period, the Company was ***scrambling to avoid FDA penalties*** for myriad changes BD had already made to Alaris without FDA 510(k) approval in clear violation of FDA regulations. Those accounts similarly reveal that BD lacked adequate quality systems and controls over critical Alaris files, including design history files regarding Alaris modifications, which also violated FDA regulations. Furthermore, throughout the Class Period, Alaris was beset with extensive, potentially dangerous, software defects, many related to improper, unapproved device changes.

14. Moreover, far from resolving limited Alaris issues in promptly-concluded discussions with the FDA, Defendants—as they admitted at the end of the Class Period and as FE reports corroborate— had been in ongoing discussions with the FDA prior to and during the Class Period about multiple Alaris issues and quality systems compliance deficiencies, including BD's failure to obtain required clearances for numerous Alaris software changes going back years. Thus, Defendants knew or recklessly disregarded that BD's discussions with the FDA were not completed—the FDA was aggressively scrutinizing Alaris-related issues, and was by no means satisfied that Alaris could be safely marketed.

15. Of critical importance to shareholders and investors, this parade of problems implicating core issues of device safety and compliance with governing law—and undergoing active FDA review—placed BD's ability to earn FY20 revenues from Alaris in severe jeopardy.

16. Even more troublingly, while Defendants were repeating their misleading representations about Alaris and BD's FY20 revenues, Forlenza and Polen were lining their pockets through illegal insider stock sales. All-in, these Defendants reaped a combined ***$58,417,985.36*** in proceeds in less than three-months of Class Period sales. Polen took home more than ***$3.749*** million in proceeds, while Forlenza pocketed in excess of ***$54.6 million*** in proceeds.

17. Then, on February 4, 2020, Defendants once more engaged in materially misleading damage control and minimized the extent to which Alaris software issues were impacting and would impact BD's revenues. Specifically, BD issued statements regarding certain software problems that could interfere with patient care. These problems, the Company claimed, would be remediated through a "voluntary recall" consisting of "education," "training," and a future software upgrade, during which, Defendants assured customers, Alaris devices could still be used.

18. Critically, the statements said nothing to even suggest that Alaris devices would not be sold, shipped, or installed during the voluntary action. Investors understood BD's February 4, 2020 statements exactly how Defendants had intended—the software issues were technical hiccups that would not impact Alaris sales or BD earnings—and shrugged. BD's stock price remained artificially inflated.

19. Defendants' three-month deception came to an end before the market's open on February 6, 2020. Then, Defendants disclosed for the first time that BD was "***continuing*** to work with the . . . [FDA]" on a remediation plan for Alaris, which would require BD to submit a comprehensive 510(k) application belatedly seeking clearance for multiple prior unapproved changes to Alaris software and all but eliminate Alaris revenues in FY20. Defendant Polen acknowledged to dumbfounded investment analysts that: (i) Alaris would be pulled from the

market due to software, device, and related quality system compliance problems; (ii) after "ongoing dialogue" with the FDA, the agency was requiring BD to seek clearances related to numerous software changes before resuming Alaris sales; and (iii) that the negative revenue impact to BD in FY20 from the loss of Alaris sales would be $400 million. Defendants slashed BD's FY20 Guidance, stating they were "revising our revenue growth guidance to 2.5% to 3.5%, ***specifically due to the Alaris situation***."

20. Upon the disclosure of the truth, BD's stock price dropped $33.74 on February 6, 2020 on unusually heavy trading volume, to close at $252.25. Analysts immediately linked the drop to the "unexpected announcement that BDX is working with the FDA on a software remediation plan for the Alaris pump system," and noted that roughly ten billion dollars of shareholder wealth had been destroyed in one day.

II. JURISDICTION AND VENUE

21. The claims asserted herein arise under Sections 10(b) and 20(a), and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and 78t-1(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

22. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and under 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false or misleading information to the investing public occurred in substantial part in this District. Additionally, Defendant BD maintains its headquarters and conducts business in this District.

24. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Lead Plaintiff

25. Plaintiff Industriens Pensionsforsikring A/S is one of Denmark's largest pension fund with at least 400,000 pensioners. As set forth in the certification attached hereto as Exhibit A, Industriens purchased or otherwise acquired BD common stock at artificially inflated prices during the Class Period and was damaged as a result of the conduct alleged herein.

B. Defendants

1. Corporate Defendant BD

26. Defendant BD is a New Jersey corporation headquartered in Franklin Lakes, New Jersey. BD is a medical technology company engaged primarily in manufacturing and selling medical devices, instrument systems, and reagents. The Company's common stock trades on the New York Stock Exchange ("NYSE") under the ticker symbol "BDX." The Company's fiscal year begins on October 1 and ends September 30 of the following calendar year, and is comprised of first fiscal quarter (October 1 - December 31), second fiscal quarter (January 1 - March 31), third fiscal quarter (April 1 - June 30), and fourth fiscal quarter (July 1 - September 30). For fiscal year 2019 ("FY19"), BD reported net income of $1.233 billion with annual revenue of $17.290 billion.

27. During the Class Period and for many years before, BD's operations consisted of three business segments: BD Medical, BD Life Sciences, and BD Interventional. BD Medical was its largest and most important segment by far. It reported operating income of $2.824 billion in FY19, $2.624 billion in FY18, and $1.907 billion in FY17 and accounted for more than half of the

Company's total revenue over the last three fiscal years: $9.064 billion in FY19 (representing approximately 52% of BD's total FY19 revenue), $8.616 billion in FY18 (representing approximately 53% of BD's total FY18 revenue), and $7.419 billion in FY17 (representing approximately 61% of BD's total FY17 revenue).

28. As also discussed below, BD acquired CareFusion Corp. ("CareFusion"), a San Diego-based medical technology company, in 2015, giving BD the right to manufacture, market, and distribute CareFusion's Alaris infusion pump system and associated technologies. This product line is often referred to collectively as the Alaris System and is described in detail below in Section IV.B.1. At all relevant times following the acquisition, Alaris was sold through BD Medical's Medication Management Solutions ("MMS") unit, which focused primarily on infusion systems and dispensing technologies.

2. Individual Defendants

29. Defendant Forlenza served as BD's Chief Executive Officer ("CEO") from October 2011 until January 2020, when he retired. Forlenza was appointed Chairman of the Board in July 2012, and currently serves as the Executive Chairman of the Board. As BD's CEO, Forlenza was responsible for the Company's day-to-day management and control. Throughout the Class Period, Forlenza approved and signed BD's periodic filings with the SEC and regularly spoke to investors and securities analysts about BD's operations.

30. Defendant Polen rejoined BD in 2009 and currently serves as the Company's CEO, a position he assumed after replacing Forlenza in January 2020. Prior to January 2020, Polen served as BD's Chief Operating Officer during the Class Period. Polen also serves as BD's President, a position he has held since 2017. In each of these roles, Polen was responsible for the Company's day-to-day management and control. Throughout the Class Period, Polen regularly spoke to investors and securities analysts about BD's operations. Moreover, from October 2014 to

April 2017, he was the Executive Vice President and President of the BD Medical Segment, during which he led the acquisition of CareFusion.

31. Defendant Reidy currently serves as BD's Executive Vice President, Chief Financial Officer ("CFO"), and Chief Administrative Officer. Reidy has held these positions since joining the Company in July 2013. As BD's CFO, Reidy was responsible for the Company's day-to-day management and control. Throughout the Class Period, Reidy approved and signed BD's periodic filings with the SEC and regularly spoke to investors and securities analysts about the Company's operations.

C. Relevant Non-Parties

32. At relevant times, Cardinal Health was a health care services company specializing in the distribution of pharmaceuticals and medical products. It acquired Alaris in May 2004 as part of its acquisition of ALARIS Medical Systems Inc. In 2009, Cardinal Health spun off CareFusion, which was then manufacturing Alaris. CareFusion operated as a publicly traded company until it was acquired by BD in 2015. While manufacturing Alaris, Cardinal Health entered into two consent decrees regarding Alaris with the FDA, discussed below, to which BD was subject throughout the Class Period.

IV. FACTUAL ALLEGATIONS OF DEFENDANTS' FRAUD

A. The Use and Regulation of Infusion Pumps

1. Background on Modern Infusion Pumps

33. Infusion pumps are electronic, external medical devices that deliver fluids into a patient's body in a controlled manner. They are commonly used to deliver blood, nutrients, or medications such as insulin, antibiotics, chemotherapy drugs, and pain relievers.

34. To function properly, infusion pumps depend on device hardware—various mechanical parts and electrical components—as well as specialized software that governs device

operations. Infusion pumps are typically operated by trained healthcare workers using a built-in software interface. Infusion pump software-based interfaces control and allow for programming of the amount, timing, frequency, limits, and other aspects of fluid delivery. Modern infusion pumps are often paired with related devices and software platforms in comprehensive "medication management" systems.

35. Further, today's smart pumps (including Alaris) rely on a range of software-based safety features, such as electronic alarms that activate when there is a risk of an adverse drug interaction, infusion interruption, or when the user sets the pump's parameters outside of pre-programmed safety limits.

36. Because infusion pumps are frequently used to administer critical fluids, including high-risk medications, hardware or software failures can have significant implications for patient safety. For instance, if an alarm indicating that an infusion is ending fails to sound appropriately due to a software error, a nurse or clinician may not receive sufficient notification that an infusion is ending. When this occurs in a high-risk population, or when the infusion provides critical or potentially risky medication, an alarm failure or other software failure could result in serious injury or death.

2. Federal Regulation of Infusion Pump Devices

37. The products, development activities, and manufacturing processes of medical device manufacturers are subject to strict regulation by the FDA pursuant to the Food, Drug, and Cosmetic Act (the "FDCA"), as amended by the Medical Device Amendments of 1976 (the "MDA").

38. The MDA separates regulated medical devices into three different classes based, among other things, on their riskiness to patients' safety. Infusion pumps, including the Alaris line, are "Class II" medical devices. According to the FDA, Class II devices possess a potential for

dangerousness and thus "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B).

39. The primary mechanism by which the FDA oversees and regulates the design and manufacture of medical devices, including changes to a device's design and software, is through the FDA's quality systems regulations. Medical device manufacturers, including BD, must establish and follow quality systems procedures to ensure that their products consistently meet applicable requirements and specifications known as current good manufacturing practice ("cGMP") standards. Importantly, regardless of whether any other specific clearance or approval is required, a manufacturer's processes related to device design and modification must always comply with all relevant quality systems regulations and related guidance.

40. The FDA requires manufacturers to document and keep records related to software or other design changes to Class II medical devices. Specifically, the FDA's quality systems regulations require that a manufacturer maintain a process whereby it documents all analysis and decisions associated with software changes to its medical devices. *See, e.g.*, 21 C.F.R.[3] § 820.30 (manufacturer must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met); 21 C.F.R. § 820.70 (manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure); 21 C.F.R. § 820.181 (manufacturer must document changes and approvals in the device master record); *see also Deciding When to Submit a 510(k) for a Software Change to an Existing Device*, U.S. Food & Drug Admin., Oct. 25, 2017.

[3] "C.F.R." refers to the Code of Federal Regulations, which is a codification of the rules established by U.S. Federal Government agencies, including the FDA.

41. If requested by the FDA, a manufacturer must be able to provide documentation and communicate in a clear and coordinated manner regarding proposed or potential changes, including software changes, to regulated devices. The manufacturer must also provide sufficient documentation regarding all related and mandatory device testing and analysis.

42. Under applicable quality systems regulations and cGMP standards, medical device manufacturers are also required to establish and maintain procedures for implementing corrective and preventive actions. These procedures include processes for, among other things: (i) detecting recurring quality problems; (ii) investigating product nonconformities; (iii) identifying actions to correct and prevent recurring nonconformities; (iv) verifying and validating corrective and preventive actions; and (v) appropriately recording all relevant information regarding quality problems and corrective and preventive action.

43. The FDA may also conduct periodic inspections at any time to determine compliance with the quality systems regulations and cGMP standards. The failure to comply with regulatory standards may result in, among other things, the issuance of a Form 483—a form used by the FDA to notify manufacturers of significant objectionable conditions or violations discovered during inspections—a warning letter, fines, seizure or recall of products, or product bans. The FDA may also seek a court order enjoining individuals and/or corporations from continuing to violate the FDCA or even recommend criminal prosecution by the Justice Department.

44. BD was required to comply with the quality systems regulations and cGMP standards with respect to Alaris at all relevant times prior to and during the Class Period.

3. The 510(k) Approval Requirement

45. As Class II medical devices, infusion pumps including Alaris must be approved for distribution and monitored with respect to device changes through the FDA's Premarket Notification 510(k) program (the "510(k) Program").

46. Under this regime, a company must submit to the FDA a 510(k) application regarding any medical device it wishes to manufacture and market: (i) when ***introducing*** a device into commercial distribution for the first time; or (ii) when there is a ***change or modification*** to a legally marketed device and that change could significantly affect its safety or effectiveness.

47. To obtain clearance from the FDA through the 510(k) Program, the manufacturer must demonstrate that its device is at least as safe and effective as, or "substantially equivalent" to, an existing device that has already been approved. When seeking to establish substantial equivalency of a new device or an existing device the manufacturer seeks to change, the manufacturer must submit a 510(k) application at least ninety days before it intends to begin marketing the device. 21 C.F.R. § 807.81(a).

48. Additional FDA regulations apply when a manufacturer is looking to change a Class II device that has already been approved. Specifically, the following situations require the manufacturer to obtain a ***new*** 510(k) approval from the FDA: (i) "[a] change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process"; or (ii) "[a] major change or modification in the intended use of the device." 21 C.F.R. § 807.81(a)(3).

49. Before the manufacturer can market the device, the manufacturer must receive an order from the FDA that clears the device for commercial distribution. Until the submitting entity receives this clearance order, it may not proceed to market the device. If the FDA is unable to

determine that a device is sufficiently safe and effective or substantially equivalent to a predicate device based upon the manufacturer's application and supporting documentation, the manufacturer will be required to resubmit its 510(k) application with new data, and the device will be barred from the market until it is cleared. *See, generally*, *Premarket Notification 510(k)*, U.S. Food & Drug Admin., https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

50. A manufacturer's responsibility for determining when a 510(k) application must be submitted with respect to a change or modification to a device is ongoing. To specifically assist both manufacturers and the FDA in determining when a software change to a Class II device such as Alaris requires submitting a 510(k) application and obtaining FDA clearance, the FDA has issued formal guidance in a document entitled *Deciding When to Submit a 510(k) for a Software Change to an Existing Device* ("FDA 510(k) Software Guidance"). The FDA issued this guidance in draft form in August 2016 and in finalized form on October 25, 2017.

51. The FDA 510(k) Software Guidance provides instruction, including flow charts, key factors, and examples regarding the various types of software changes that clearly require new 510(k) clearance. Such changes include where: (i) "the change introduce[s] a new risk or modif[ies] an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device"; (ii) "the change create[s] or necessitate[s] a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm"; or (iii) "the software change could significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device."

52. Critically, the FDA 510(k) Software Guidance makes clear to manufacturers that even if a given change does not itself require 510(k) clearance, the ***cumulative*** impact of discrete software changes over time can result in the modified device no longer being substantially equivalent to a predicate device. In that circumstance, a new 510(k) clearance is required. For instance, the FDA 510(k) Software Guidance includes a specific example concerning infusion pumps reliant on software, like Alaris, to which additional alarm systems are added.[4] The FDA 510(k) Software Guidance specifically explains that in such an instance, the manufacturer ***is required to submit a new 510(k)*** because the change modifies the existing safety-related risk control—the alarm already present—by adding an additional risk control, the second alarm.

53. In contrast, the FDA 510(k) Software Guidance identifies other, limited software changes as not requiring a new 510(k) submission and clearance, such as "a change made ***solely*** to strengthen cybersecurity" or "a change to the software [that] ***only*** restores the device to the specifications of the most recently cleared device." Even in the case of a clearly non-substantive change falling outside of the 510(k) clearance requirement, that change must continue to comply fully with the FDA's quality systems regulations and cGMP standards.

4. Product Recalls

54. In addition to imposing stringent quality systems, cGMP, and 510(k) clearance standards on manufacturers ***before*** a new or altered Class II medical device can be distributed, federal regulations provide a mechanism by which risks and defects in devices that appear ***after*** such clearance is obtained can be effectively addressed. This mechanism is the product recall.

[4] The example describes a situation where "[a] general purpose infusion pump has one alarm to alert the user when an occlusion [blockage or closing of a blood vessel] has been detected. The software change modifies the existing alarm to provide two alarms related to occlusion: occlusion downstream and occlusion upstream. These alarms provide specific information to help resolve the occlusion."

55. The FDA requires medical device manufacturers, including BD, to monitor adverse events and product defect reports and to redress identified product defects. Specifically, the FDA directs that when a company learns of a defect in one of its medical devices, it may do one of three things: (i) propose a correction; (ii) remove the product from the stream of commerce; or (iii) voluntarily recall the product. The FDA uses the term "recall" when a manufacturer takes a correction or removal action to address issues with a medical device that violates FDA requirements. Corrections related to voluntary recalls may be implemented while the device continues to be marketed and remains in use and available in the field.

56. According to the FDA, a recall is appropriate when a medical device is defective, or could be a risk to health, or when it is both defective and a risk to health.

57. The FDA classifies recalls based on the degree of risk associated with the defective device. A Class I designation is the most serious and indicates that there is a reasonable chance that a product will cause serious health problems or death. A Class II designation indicates that a product may cause a temporary or reversible health problem, or where there is a slight chance that it will cause serious health problems or death. A Class III designation indicates the defective product is not likely to cause any health problem or injury. Once a recall is classified and issued, the FDA monitors device recalls to ensure that the recall strategy is effective.

5. FDA Mandates Strict Adherence to Adverse Event Monitoring, Compliance, and Inspection Requirements With Respect to Infusion Pumps

58. In 2010, following a review of reported adverse events related to infusion pumps and recalls of such devices—including Alaris (discussed below in Section IV.B.2)—the FDA determined that there was a specific need to tighten regulatory oversight of infusion pumps. It found that "many injuries and adverse events may be avoided by improving the design verification

and validation processes" (key aspects of quality systems and cGMP) applied to infusion pump devices.

59. To accomplish its aim, the FDA announced the Infusion Pump Improvement Initiative. As part of the Initiative, the FDA took three steps to improve infusion pump safety: (i) increase user awareness; (ii) proactively facilitate device improvements; and (iii) publish new guidance for industry. The FDA indicated that surveillance through adverse event monitoring and manufacturer inspections was to be an important part of identifying safety issues with pumps already on the market.

60. On April 23, 2010, the FDA issued new draft industry guidance entitled *Infusion Pump Total Product Life Cycles* ("Infusion Pump Guidance"), which reported that the most frequently reported infusion pump problems included "software error messages . . . broken components, battery failure, alarm failure, and over infusion and under infusion."

61. The FDA also issued a letter to infusion pump manufacturers, reporting that it had seen an "increase in the number and severity of infusion pump recalls." The FDA explained that from January 1, 2005 to December 31, 2009 it "received over 56,000 [medical device reports] associated with the use of infusion pumps. Of these reports, approximately 1% were reported as deaths, 34% were reported as serious injuries, and 62% were reported as malfunctions." Echoing the Infusion Pump Guidance, the letter noted that "[t]he most frequently reported external infusion pump device problems [we]re: software error messages . . . broken components, battery failure, alarm failure, over infusion and under infusion."

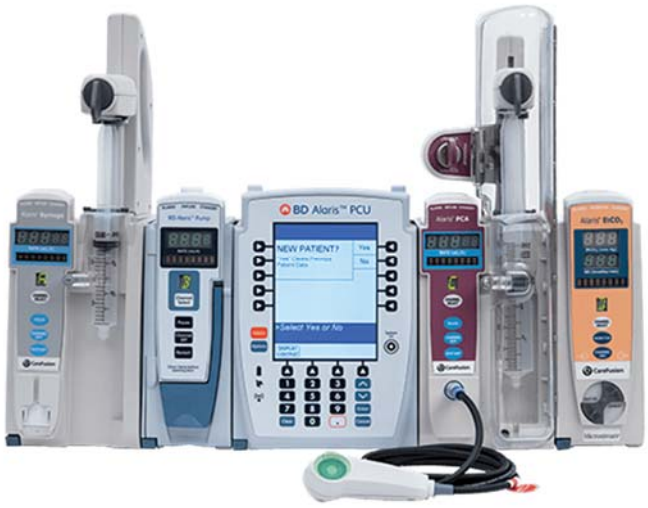
62. Explaining that it had "evaluated and analyzed" these problems and believed the "problems are preventable," the FDA specifically notified infusion pump manufacturers that they "need to conduct additional risk assessments of new products or ***changes to products currently***

being marketed." The letter also advised infusion pump manufacturers that the FDA "strongly recommend[ed] external infusion pump manufacturers meet with the Agency early in the device development process to discuss submissions ***regarding … changes to existing devices***."

B. Alaris's Troubled Past

1. The Alaris Infusion Pump

63. Alaris is an infusion pump and vital signs monitoring system. Below is a picture of a built-out Alaris system:



64. The center module is the Alaris PC Unit (the "PC Unit") (Model Nos. 8000 and 8015), which provides the main user interface and power supply for the associated infusion and monitoring modules. Every Alaris infusion system starts with the PC Unit. The PC Unit has wireless data transfer capabilities to ensure access to up-to-date information. Healthcare professionals can build a specialized infusion pump by attaching various infusion modules to the PC Unit depending on the type of medication and precision of infusion flow required. The screen and keyboard allows clinicians to gather, analyze, and respond to intravenous medication data.

65. Clinicians can attach up to four pump modules to a single PC Unit, allowing four different infusions. There are three primary infusion modules: (i) the standard pump, Alaris Pump

Module (Model No. 8100), which allows for continuous or intermittent delivery of fluids, medications, blood, and blood products to adult, pediatric, or neonatal patients; (ii) the precision pump, Alaris Syringe Module (Model No. 8110), which syncs with the PC Unit and combines precision instrumentation to help ensure accurate medication delivery of fluids, medications, blood, and blood products using continuous or intermittent delivery; and (iii) the specialized module for pain medication, Alaris PCA (Model No. 8120), which has additional safety features, such as respiratory monitoring, and allows patients to press a button to receive additional medication. Each module utilizes software that may periodically require updates.

66. As explained in more detail below, Alaris is compatible with several other BD Medical products and is the cornerstone of the multi-device medication management suite whose horizontal integration or "interoperability" (as BD called it) the Company touted to the market.

2. Alaris's History of Regulatory Violations and Scrutiny

67. The fact that Alaris was suffering from dangerous product defects and critical quality systems deficiencies during the Class Period (as Defendants knew) was in fact consistent with the device's spotty quality and safety history. Indeed, prior to the Class Period, both before being acquired by BD and after, Alaris was subject to numerous serious product recalls and two consent decrees with the FDA.

68. Specifically, on August 15, 2006, Cardinal Health, which then manufactured Alaris, initiated a recall of numerous Alaris models due to the potential for over-infusion caused by a software issue with the keypad. (The software defect resulted in "key bounce," i.e., when a keyboard entry registers twice while pressing the key once. For instance, an infusion rate intended to be 4.0 mL/hr where a key bounce occurs, results in an entry of 44.0 mL/hr). As part of the recall, letters and warning labels were sent to the customers of approximately 140,000 pumps. The FDA classified it as a Class I recall.

69. Almost immediately, on August 23, 2006, the U.S. Attorney for the Southern District of California filed a forfeiture complaint in United States District Court for the Southern District of California. The Complaint alleged that the products were adulterated under the FDCA because the pump quality was substandard, and detailed the FDA's inspection of the Alaris manufacturing facility that had uncovered multiple violations of cGMP and the quality systems regulations, including failures to: (i) identify the actions needed to correct and prevent recurrence of non-conforming product and other quality problems; (ii) adequately investigate the cause of non-conformities relating to product, processes, and the quality system; (iii) maintain complaint handling procedures that adequately define and document the complaint receipt and review step; and (iv) adequately establish and maintain procedures to implement corrective and preventive actions.

70. On August 28, 2006, Cardinal Health suspended production, sales, and repairs of the Alaris SE pump after approximately 1,300 units were seized by the FDA.

71. In order to resolve the Justice Department's complaint, Cardinal Health entered into a consent decree with the FDA on February 7, 2007 (the "Consent Decree"). The Consent Decree outlined the processes Cardinal Health was to follow to resume manufacturing and sales of Alaris SE pumps. The steps included submitting a plan to the FDA outlining corrections for the pumps currently in use, submitting a remediation plan for the seized pumps, and engaging an independent expert to inspect Alaris facilities and certify Cardinal Health's infusion pump operations.

72. In June 2007, just months later, Alaris pumps were subject to two Class II recalls related to manufacturing defects and sterilization failures. Then, in October 2007, Cardinal Health initiated yet another Alaris recall—the year's third Alaris recall. This recall impacted approximately 200,000 units, which were at risk for inaccurate flow rates caused by assembly and

manufacturing defects. Given the severity of the defects and malfunctions, this recall received the FDA's Class I designation on January 4, 2008, reflecting the defects' risk of causing serious injury or death to patients.

73. Days later, the FDA conducted a multi-day inspection of the Alaris design and manufacturing facilities. Running from January 8, 2008 to February 1, 2008, the inspection uncovered multiple violations of cGMP and the quality systems regulations, which the FDA reported in a Form 483 dated February 1, 2008.

74. Following this succession of defects and violations in connection with Alaris devices, the Consent Decree was amended in February 2009 to include ***all*** Alaris infusion pumps then produced (the "Amended Consent Decree"). Under the Amended Consent Decree, the FDA determined once again that certain Alaris products were adulterated.

75. Moreover, Cardinal Health was required to conduct a thorough review of ***all Alaris infusion pumps*** within sixty days and submit a corrective action plan to the FDA that outlined all planned modifications to any pump products. Additionally, within 100 days, Cardinal Health was required to have an independent expert inspect and certify that the company's infusion pump operations were in conformity with the quality systems regulations and that the company's recall procedures and ongoing infusion pump recalls were in compliance with the FDCA.

76. On April 24, 2009, Cardinal Health submitted the corrective action plan required by the Amended Consent Decree to the FDA. In the plan, Cardinal Health disclosed that there was a software problem with the Alaris PCA module and Alaris PC Unit operating with software versions 8 through 9.1 and proposed a software correction to the FDA. The software correction required 510(k) clearance. In March 2009, Cardinal announced a shipping hold for the Alaris PCA modules and Alaris PC Units pending 510(k) clearance.

77. In a July 10, 2009 press release, Cardinal Health announced it had resumed shipping of Alaris PC units and PCA Modules after receiving 510(k) clearance from the FDA for the software change. The release explained: "***The 510(k) clearance for our software correction is another important milestone in our continued progress under the amended consent decree***." Soon thereafter, Cardinal Health spun off CareFusion, which continued to manufacture and market Alaris while operating as a standalone company.

C. Despite Alaris's Checkered Safety History, BD Acquires Alaris—Then Stops Obtaining 510(k) Clearance for Subsequent Design Changes Prior to the Class Period

1. BD Buys CareFusion, Touting Alaris and the Company's New Strategy to Lead the Medication Management Market

78. In full view of Alaris's distressed past—and the requirements of the Amended Consent Decree—on October 5, 2014, BD entered into an agreement and plan of merger with CareFusion. Through the acquisition, the Company would acquire CareFusion's principal product lines, Alaris and the Pyxis automated dispensing system (an automated movable cabinet that stores prescription medications accessed only by healthcare providers).

79. BD closed its acquisition of CareFusion for $12.2 billion on March 17, 2015, with CareFusion becoming a wholly-owned subsidiary of the Company. CareFusion was absorbed into the BD Medical segment, doubling its size.

80. Since acquiring CareFusion, BD has manufactured Alaris, Pyxis, and numerous supporting products, which operate in conjunction with and depend on Alaris pumps. After closing on the CareFusion acquisition, in a March 17, 2015 investor presentation entitled "A Leader in Medication Management and Patient Safety," the Company hailed Alaris and Pyxis as "Key Brands" that would now make up BD's "Key Platforms."

81. Together, BD proclaimed the acquired devices would drive BD Medical's MMS unit. In addition, the Company told investors it would leverage its Alaris and Pyxis platforms together by connecting them though the HealthSight Viewer, a web-based pharmacy operations database that combines data from the Pyxis and Alaris infusion systems into a single view. According to the Company, this interoperability enabled BD to provide "end-to-end solutions" for pharmacy to patient tracking, which hospitals desire as a means to identify bottlenecks in pharmacy fulfillment, optimize medication availability, and provide visibility into errors and medication theft.

82. Alaris was the linchpin to BD's growth strategy in what was now its largest operating segment, and the Company promoted Alaris and a related suite of BD products that offered "interoperability" with Alaris as a key to its success in the medication management space. According to the Company, when a consumer bought one of the devices in the suite, the interoperability feature would make it more likely that they would buy the others as well.

83. Notably, at all relevant times from the acquisition of CareFusion through the end of the Class Period, Defendants knew BD was subject to the Amended Consent Decree as to all Alaris pumps, as the Company acknowledged in its 2019 Form 10-K:

> [The Company] . . . remains subject to the amended consent decree, which includes the requirements of the original consent decree . . . . However, we cannot predict the outcome of this matter, and the amended consent decree authorizes the FDA, ***in the event of any violations in the future***, to order us to cease manufacturing and distributing infusion pumps, recall products and take other actions. We may be required to pay damages of $15,000 per day per violation if we fail to comply with any provision of the amended consent decree, up to $15 million per year.

2. BD Stops Obtaining FDA Regulatory Clearance for Changes and Modifications to Alaris

84. Throughout the Class Period and for years prior, BD publicly acknowledged that its medical devices including the Alaris pump were subject to the FDA regulatory structure oversight and requirements discussed above.

85. For example, BD discussed the FDA's expectations in its 2019 Form 10-K and characterized as contingent the possible consequences of non-compliance with FDA regulations:

> Following the introduction of a product, [the FDA] . . . also periodically review[s] our manufacturing processes and product performance. ***Our failure to comply with the applicable good manufacturing practices, adverse event reporting, and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, warning letters or consent decrees, closure of manufacturing sites, import bans, seizures or recalls of products and damage to our reputation. More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk***.

86. In compliance with the requirements imposed by FDA regulations, Alaris's previous manufacturers had sought regulatory clearance for changes to Alaris, including software modifications, in the years before BD acquired the device.

87. Alaris first received 510(k) clearance on June 21, 1995 (Model No. K950419). At that time, the pump was manufactured by IMED Corp. and marketed as The IMED Orion Infusion Pump and Administration Sets.

88. The FDA 510(k) Premarket Notification database reflects that since 2002, six different 510(k) applications were filed for Alaris changes and modifications, including 510(k) applications specifically related to Alaris software changes. For instance, in 2009, the FDA granted a 510(k) clearance for the Alaris PC Unit, Model No. 8000, which, according to then-manufacturer Cardinal Health, specifically related to a software change and correction in the pump. For each of the various Alaris 510(k) applications the different manufacturers submitted before and during

2014 (all of which related to device changes), the FDA issued a letter finding the device to be substantially equivalent to a predicate device and cleared Alaris for commercial distribution.

89. Defendants acknowledged on February 6, 2020 that BD had made myriad software changes to Alaris since the Company acquired it. Remarkably, however, a review of the FDA 510(k) Premarket Notification database in August 2020 indicates that no 510(k) clearance had been obtained with respect to Alaris since August 2014, prior to BD's acquisition of CareFusion. In other words, through at least the end of the Class Period, BD did not obtain 510(k) approval for software change it made to Alaris pumps ***at any time*** since it acquired CareFusion and Alaris rights in March 2015.

3. Product and Compliance Issues, Including Software Defects, Continue to Plague Alaris

90. The safety problems, compliance issues, and product defects that had long hampered Alaris continued after BD acquired CareFusion in 2015.

91. In 2016 alone, the FDA classified five Alaris infusion module recalls as Class II.

92. In 2017, the FDA posted five more recalls of Alaris modules, four Class II and one Class I. As the Company disclosed, three of the 2017 Alaris recalls impacted large numbers of units, of which many of the issues specifically related to software defects.

93. ***First***, in January 2017 the FDA designated as Class I—the highest risk recall—a recall initiated by BD in December 2016 that impacted over 380,000 Alaris Pump Module (Model No. 8100) units. The problem was caused by a software error that resulted in a false "Air-in-Line" alarm sounding despite there being no air in the line. Once the alarm sounded the infusion of medication, blood, or nutrients was interrupted. As a result of the critical software problem, BD sent a "Medical Device Safety Notification" letter to all affected customers.

94. ***Second***, in March 2017 the FDA designated as Class II an Alaris recall initiated by BD in November 2016. The recall impacted over half a million Alaris PC Units (Model Nos. 8000 and 8015) and was caused by another software error that resulted in the low battery and very low battery alarms failing to trigger. When functioning properly the low battery alarm would activate when thirty minutes and five minutes of estimated battery runtime remained. The software error resulted in no alarms sounding prior to the battery discharge alarm, which indicates that the battery is depleted. This failure caused the device to immediately shut down, stopping the infusion. The software error and defect underlying this recall was ***never*** adequately corrected prior to the end of the Class Period.

95. ***Third***, in June 2017 BD confronted another Alaris software error, impacting over half a million Alaris PC Units (Model No. 8015) with software version above 9.12. The error precipitated at least five scenarios which could result in the occurrence of "Systems Error Code 255-16-275" in the device, and interrupted infusions. The FDA classified this recall as Class II on June 19, 2017. This software error was also never fully corrected as of the end of the Class Period.

96. Further, on April 13, 2018, BD initiated a recall of the Alaris Pump Module (Model No. 8100) after the pump suffered a major mechanical failure. The recall, which the FDA classified as a Class I recall in July 2019, impacted approximately 600,000 Alaris units manufactured between April 2011 and June 2017 that had bezels manufactured with FR-110 plastic. The manufacturing process resulted in a bezel with weakened plastic, which, over time, led to separation of the bezel post. Such separation resulted in critical errors such as free flow, over infusion, under infusion, or interruption of infusion. In order to correct the defect, BD was forced to contact all Alaris customers affected and send a technician to manually replace the bezel in

impacted units. Overwhelmed with the time and labor involved in remediation, BD developed a priority system to attempt to correct the units.

97. Notably, by the start of the Class Period, the FDA was already highly focused on product defects impacting infusion pump alarm systems. In or around June 2019, one of the Company's competitors in the infusion pump business, Fresenius Kabi USA, issued a voluntary recall of its infusion pump following a software failure that caused a "Keep Vein Open (KVO), End of Infusion" alarm to malfunction (Alaris suffered from a similar malfunction, as detailed herein at ¶¶ 172-78). The FDA classified the recall as Class I on August 12, 2019, explaining that the software failure could result in under-infusion or over-infusion, which could lead to death or serious injury. Thus, in August of 2019, just a few months before the Class Period began, the FDA warned that "***KVO alarms should be high priority***."

4. Leading Up to the Class Period, Defendants Laud Alaris's Value to BD's Performance and Growth Strategy

98. Heading into the Class Period, BD repeatedly touted the commercial success of Alaris, and Alaris's integral role in driving revenue growth in the Company's key BD Medical segment and MMS unit, and for the Company as a whole.

99. For example, in its 2018 Form 10-K, dated November 21, 2018, BD asserted that the "Medical segment's underlying revenue growth was largely driven by sales of" two product groups, one of which was "dispensing and infusion systems."

100. Given its importance to BD's revenue and overall growth strategy—including its ability to drive revenue through complementary products marketed by BD—investors and investment analysts were keenly focused on Alaris.

101. For example, on a January 3, 2019 investment analyst conference call, a research analyst from Goldman Sachs asked Defendant Forlenza, "tell us a little bit about in the pump

business, kind of where you are from a competitive standpoint?" In response, Forlenza stated "[w]e're doing quite well in the pump business," going on to emphasize that Alaris was "adding to our momentum," had done "exceptionally well," and was integral to a suite of other "interoperab[le]" BD products, thereby further driving Alaris revenue:

> That is—and that is ***adding to our momentum***. You saw that momentum in the fourth quarter in that business, both pumps and the cabinetry on the dispensing side did well, but the pumps did ***exceptionally well***. But ***bigger driver*** [sic] ***is the connectivity, the interoperability*** side of this with the pharmacy and all the workflow and safety improvements that you're getting out of that. So, in 2018, we continue to gain share, expect that, ***that business will continue to do quite well in 2019***. As the interoperability part is now part of the bigger health site, informatics that we have over the entire system,[5] including the pharmacy, the compounding, the pumps, the cabinetry and all of that. So as we build that complete system, the ***pumps are a vital part of that***. So doing quite well.

102. During BD's earnings call for the first quarter of FY19, held February 5, 2019, Defendant Forlenza again highlighted Alaris, stating "on the Medical side, we're expecting continued strong growth in MMS as we do well, both in dispensing, but in—***particularly on the pump side of things***." Alberto Mas, BD's Executive Vice President and President of the Medical Segment, added: "On the infusion side, we're seeing continued above-market growth. . . . A lot of that has to do with great acceptance of our refreshed Alaris M2 pump."

103. Investment analysts lauded and accepted BD's representations about expected continued growth in Alaris-related revenue for BD Medical and the Company. As one example, during the June 13, 2019 Goldman Sachs Global Healthcare Conference, one analyst commented: "You've seen tremendous share momentum here with Pyxis and pumps."

[5] That product suite included the Alaris pump, the Pyxis MedStation (the automated medication dispensing cabinet), and HealthSight Viewer—software that connected Pyxis and Alaris for data analytics purposes.

104. Then, on August 6, 2019, BD held its FY19 third quarter earnings call, during which Defendant Polen again touted the MMS business, noting the "really strong number in MMS this quarter as well, which is reflecting the continued momentum that we see in that business." Moments later, Mas elaborated, explaining that "the drivers are the ones that we had mentioned in the past in terms of our core platforms in [Q]2, Alaris, Pyxis ES."

105. Days before the Class Period, investment analysts covering the Company continued to broadly accept Defendants' representations about Alaris driving revenue growth in BD Medical and the Company overall. For example, in an equity research report on BD dated November 1, 2019, analysts at Cowen identified "continued momentum and share gains from Alaris infusion pumps and Pyxis ES" as a "tailwind" for the business that supported a projection of annual revenue growing to well over $9 billion in the BD Medical segment. Similarly, in an equity research report dated November 4, 2019, investment analysts from Zacks highlighted "BD's Alaris Pump" as one of the products that "***continue to drive the company***."

D. The Class Period Begins: Defendants Mislead Investors About BD's Performance and Growth Prospects, Downplaying Product and Compliance Issues and Ongoing FDA Scrutiny Relating to Alaris

1. Defendants Issue Ambitious FY20 Guidance While Telling Investors that Alaris Revenue Will Be Briefly Delayed as Mundane Software "Improvements" Are Completed

106. Defendants' positive statements about Alaris's contributions to BD Medical and BD's bottom line and growth prospects continued into the Class Period. On November 5, 2019, the first day of the Class Period, BD announced its full FY19 earnings and issued FY20 Guidance.

107. In announcing BD's FY19 results, Defendant Reidy stated that "BD Medical revenues grew 5.3% in the fourth quarter and 5.1% for the full fiscal year. As expected, fourth quarter performance in the Medical segment was ***driven by ongoing momentum and share gains***

in Medication Management Solutions [MMS] and continued strength in Pharmaceutical Systems."

108. Defendants Forlenza and Reidy then announced BD's FY20 Guidance, which included revenue growth of 5% to 5.5% and earnings per share between $12.50 and $12.65. Focusing investors' attention specifically on BD Medical, Reidy added that the Company was forecasting lofty revenue growth of 4% to 5% in that segment alone.

109. Defendant Reidy also told investors that BD's overall revenue growth would be approximately 1% lower in the first half of FY20 than the full fiscal year's revenue growth of 5% to5.5%. He explained that the first half's lower guidance was owed to expected "first quarter revenue growth of 1% to 2%." Reidy further explained that the lower first quarter FY20 growth was due to a temporary delay in Alaris shipments due to "***improvements***" and "***upgrades***" to Alaris software to take place in the first quarter.

110. Defendant Reidy then assured investors that the Alaris software changes would simply "***move the timing of some sales from Q1 to the balance of the fiscal year***." After this temporary delay in Alaris shipments, he claimed, Alaris sales would return, allowing BD to meet its FY20 Guidance.

111. Defendant Reidy further stated that BD was engaged in discussions with the FDA regarding mere implementation questions: "We are in discussions with the FDA about the timing of implementation of these upgrades and the possibility of bundling them with a new software version release." At no point did Reidy or any other BD official even suggest that these FDA discussions would not be resolved and the software "upgrades" implemented, by the end of first quarter FY20.

112. Analysts pressed Defendants for information concerning Alaris and BD's FY20 outlook. In response, Defendant Polen proclaimed Alaris was the "clear leader and product choice" in the infusion space and MMS segment and represented that the software changes were positive, routine, and would cause "no slowdown" in Alaris's "momentum":

> As you know, Alaris is the clear leader and product choice in, not only the infusion market, but also as part of a broader Medication Management Solution that our customers are investing in. And ***it's part of our process and our strategy in the business to continually iterate and make enhancements to the platform***. And so you've seen us do that certainly on the hardware side with significant investments, such as the new Alaris M2 pump launch, which has been extremely well received by our customers. ***And we've been making those same type of investments in software upgrades over the last couple of years. And this upgrade right here is a continued reflection on those investments and will be forthcoming.***
>
> I would just say in terms of momentum, maybe just one other comment there on your question, we saw in FY '19 near or at, I'd say, record levels of continued share gain both in the infusion and the dispensing business, so about 200 basis points of gain in infusion and 100 in dispensing. And ***we see no slowdown in that momentum***.

113. Analysts and market commentators had not expected the news concerning deferred Alaris sales, shipments, and revenue, but accepted Defendants' representations about the reasons for the temporary pause in Alaris shipments and Alaris's strong "share gain" prospects in FY20, after the Alaris "improvements" and "upgrades" were completed in first quarter FY20. Notably, analysts expressed assurance about BD's ability to meet the FY20 Guidance.

114. For example, in a November 5, 2019 report, investment analysts at J.P.Morgan wrote that the "initial top-line guidance of 5.0-5.5%cc [constant currency] [w]as a conservative baseline for the company" and that:

> Looking specifically at quarterly sales growth cadence in FY20, management is pointing towards F1H revenue growth 100bps below the full-year range and F1Q growth of only 1-2%cc ***as the company implements improvements to the Alaris pump that will move sales from F1Q to the balance of the year***. This implies F2Q growth of ~5.5% or so, and 2H growth in the range of 6-6.5%cc sales growth.

115. Similarly, in a post-earnings call research report on November 5, 2019, RBC Capital Markets analysts reflected Defendants' claims about temporary Alaris revenue delays, stating that while FY20 revenue was "expected to be more back-end weighted than we had anticipated," ***"[w]e believe that BDX can still grow FY20 revenues ~5%+ y/y, driven by new/upcoming products . . . as well as continued share gains in MMS***."

116. That same day, investment analysts at UBS also reiterated Defendants' claims on the earnings call, reporting that while "Alaris software and features update will adversely impact BDX's topline by 1-2% points. ***Management expects a catch up through the course of the year***."

117. Wells Fargo likewise noted on November 5, 2019 that the sales growth "deceleration" discussed on the call reflected "impact of ***order timing*** related to the pending Alaris pump ***software upgrade***." Wells Fargo reiterated Defendants' representations about Alaris shipping delays moving sales out of first quarter FY20 and into the rest of FY20, noting that "***timing of Alaris pump software upgraded in the US will push sales into FQ2-FQ4***."

118. Based on the November 5, 2019 earnings release and "additional color" provided by BD executives in private meetings on November 6, 2019 that included Defendants Forlenza, Polen, and Reidy, a November 14, 2019 J.P.Morgan report noted "delayed shipments of the Alaris pump that were pushed out to F2Q from F1Q, which is ***a timing issue rather than a read-through to underlying demand***."

119. Consistent with Defendants' claims about the temporary Alaris ship-hold and the mere one-quarter shift in Alaris revenue, J.P.Morgan parroted Defendants' misleading explanation for the delay:

> ***On the pump side, we remain bullish on Becton's ability to continue capturing share despite this delay in revenue. An FDA initiative to standardize alarm configuration on pumps is the main reason why Becton has postponed the shipment of some orders, as the company would rather upgrade the pumps and***

> ***then ship them rather than vice versa***. With underlying demand and orders stable, we see Becton as well positioned to post another year of share gains in FY20 (200-300bps in FY19) as it continues to boast a superior comprehensive offering within Medication Management. The integration between Alaris and Pyxis (compounding and supply) represents a meaningful value add for hospital systems, and one that competitors continue to lack.

a. Behind the Scenes, Defendants Ignore Mounting Compliance and Product Issues that Severely Jeopardize Alaris Revenue

120. Even as they championed Alaris as a driver of BD's robust growth and FY20 Guidance, Defendants knew of or recklessly disregarded extensive compliance issues and widespread—and potentially dangerous—software defects with respect to Alaris that materially undermined such representations.

121. As shown below, these undisclosed facts and BD's ongoing discussions with the FDA regarding their urgent remediation rendered BD's FY20 Guidance and accompanying statements on November 5, 2019 and throughout the Class Period false and misleading. For example, these facts belied Defendants' claims that the Alaris ship-hold was merely a fleeting, several-week delay related to a limited question of implementing software "improvements" and that Alaris sales would soon return so vigorously as to drive BD to meet the FY20 Guidance.

122. Defendants understood the acute threat that BD could be prevented from resuming Alaris shipments (and thus from realizing Alaris revenue) for far longer due to at least two related reasons

123. *First*, Defendants had blatantly ignored the FDA's 510(k) approval process and related guidelines for years. Defendants' admissions and the first-hand accounts of Former Employees demonstrate that during the Class Period, BD was scrambling to avoid FDA penalties for myriad changes BD had ***already made*** to Alaris ***without*** FDA approval, in clear violation of FDA regulations. As explained in Section IV.A.3, absent the FDA's clearance, BD was barred from marketing those products.

124. As explained in Section IV.A.3, FDA regulations required BD to submit a 510(k) application at least ninety days ***in advance*** of marketing any Alaris product it changed in a way that could significantly affect its safety or effectiveness. Absent the FDA's explicit clearance, BD was barred from marketing those products.

125. FE-1, a senior engineer at BD from 2015 to 2019, worked directly on software changes to Alaris. He stated that during the course of his employment, BD made modifications to Alaris to address "core anomalies," which affected the Alaris pump's performance.

126. FE-1 explained that when BD made modifications to Alaris, BD's Regulatory Department would make a determination of whether the change was "in-scope or out-of-scope," with the latter requiring BD to obtain 510(k) approval.

127. According to FE-1, Alaris received software updates wirelessly. He reported that BD took the position that some of the software modifications did not require 510(k) filings because the modifications were not directly changing the physical existing infrastructure of the pump.

128. FE-1 recalled that by early- to mid-2019, BD's Regulatory Department "came to the realization" that many prior Alaris changes and/or modifications had ***required but never received FDA 510(k) clearance***. He explained that BD was therefore ***actively attempting to address and correct the filing issues by no later than early-to-mid-2019***.

129. FE-2, who worked at CareFusion and then BD until early 2019 in Operations Quality and Quality Systems, had responsibilities for managing BD's quality systems. He recalled discussions at weekly staff meetings held by Keith McLain, Head of Quality, concerning BD's need to seek 510(k) approval for a backlog of software changes it had made to Alaris.

130. FE-1 said that to address the issue, he understood that the Regulatory Department attempted to file during mid-2019 a "catch-up" 510(k) filing that encompassed all of the un-filed

changes and modifications. This filing, according to FE-1, attempted to obtain approval ***retroactively*** for all of the corrections, modifications, and software patches BD had ***already made*** to Alaris products in a single blanket filing. FE-1 understood that this filing was rejected by the FDA.

131. FE-1 noted that, in general, if the FDA rejected a 510(k) filing on a feature that had been added to Alaris, the pump could not ship with that feature. FE-1 stated "I don't think it was a secret" at the Company that BD was having registration issues with modifications made to the pump. FE-1 further explained that BD had "a habit of sitting on the issues related to the pump."

132. FE-3, an Associate Director in engineering at BD from mid-2016 through late 2019, worked directly on Alaris in that capacity. He stated that ***BD avoided seeking 510(k) approval because filing 510(k)s would alert the FDA that the Company was behind in seeking the required clearances for changes or modifications already made to Alaris***.

133. Thus, Defendants misrepresented and downplayed their ongoing discussions with the FDA as a simple question of when the FDA would greenlight new Alaris software upgrades—when they knew Alaris was in fact on the market having undergone multiple significant software changes over time that required, but had not received, 510(k) clearance from the FDA. At best, Defendants were reckless in failing to investigate the very topic on which they spoke.

134. *Second*, a range of serious product defects continued to affect Alaris throughout the Class Period. As discussed below, some of these defects forced BD to halt Alaris product shipments.

135. To this end, FE-3 recalled learning in 2019, before the Class Period, that there were numerous "trackers" concerning "bugs" or defects in Alaris products that required BD's attention. He explained that these trackers were old—some had existed for eight years or more. FE-3

understood that when an FDA auditor learned of these trackers during the course of an audit in 2019, ***Alaris product shipments were put on hold by no later than October 31, 2019***.

136. Specifically, FE-3's Director told him on October 31, 2019, that BD was going to put a ship-hold on Alaris.

137. FE-1 believed the FDA's rejection of the Company's "catch-up" 510(k) (discussed above) was a reason for the limitation on the sales of Alaris (i.e., the ship-hold).

138. FE-3 recalled that every time he gave pushback regarding issues with Alaris, he was kicked out of meetings or told to keep his mouth shut to keep his job.

139. Moreover, at the time of Defendants' statements on November 5, 2019 (and thereafter), BD was struggling to remediate long-standing software defects in Alaris products that were subject to recalls years prior, including in 2016 and 2017.

140. These and related product defects, eventually largely admitted by Defendants and corroborated by BD's former employees, rendered Defendants' Class Period statements materially false or misleading.

141. For example, Defendants' claims that BD was simply making "improvements" to Alaris "software" and "upgrades to alarm prioritization and optimization" misrepresented and misleadingly minimized Defendants' behind-the-scenes efforts to remediate Alaris's longstanding defects and to belatedly seek FDA clearance for numerous Alaris software changes that had already been implemented in marketed devices.

142. Defendants also misled investors when they assured them in November 2019 that these same "improvements" would cause a temporary pause in Alaris revenue affecting only first quarter FY20. As Defendants knew, unapproved software changes and pervasive product issues of

which the market was unaware clouded BD's ability to ship and sell Alaris indefinitely, especially in light of the strict terms of the Amended Consent Decree.

b. BD Maintains Deficient Quality Systems as Applied to Alaris

143. Significant deficiencies and compliance failures in BD's quality systems as applied to Alaris also jeopardized Alaris revenues in FY20. Defendants acknowledged this fact after the Class Period, stating that the Company's "infusion quality process and system . . . did not meet FDA's expectations." Statements by Former Employees reveal Defendants, in fact, knew or had access to information reflecting this fact throughout the Class Period.

144. Quality systems requirements and related guidelines dictate that, regardless of whether a 510(k) is required, manufacturers must document all analysis and decisions associated with software changes. Hence, Defendants were required to keep and have access to records documenting all analysis and decisions associated with software changes to Alaris.

145. FE-4 worked at BD from mid-to-late 2019 as a Quality Assurance Manager with a primary responsibility of conducting reviews of quality systems at several Alaris production facilities. FE-4 explained he was specifically hired in mid-2019 to help BD prepare for an anticipated FDA inspection.

146. To conduct a review of quality management processes and quality systems, FE-4 stated he would focus on documents the FDA might look at to determine what documents were missing or would need to be remediated. FE-4 explained that BD was supposed to maintain documents illustrating that the production of Alaris pumps was being done in a uniform fashion and in accordance with the regulatory requirements set forth for the medical device industry.

147. Overall, FE-4 stated that BD's records were a mess, with many missing. His review of Alaris files uncovered numerous document deficiencies, including many instances of missing records that would need remediation. According to FE-4, there were instances in which the pump

was modified as the result of a defect or other issue and the records were incomplete—or completely absent.

148. To this end, FE-4 specifically referenced Alaris records dating back to the pumps' original design, including the "Design History File." He stated that the lack of documentation for that file was particularly troublesome. He explained that if there was an issue with the product, the first thing one does is look to the original design to make sure the parts were all in specification. Without the design file, this was not possible.

149. In another example, FE-4 stated that he could not find any record of the design specifications being provided by BD to the supplier of a particular part used in the Alaris pump, which presented the risk that the supplier designed the part to its own specifications and not in accordance with BD's requirements. As a result, FE-4 explained there was "no way to confirm" this part was manufactured to required standards.

150. FE-4 further explained that two separate "GAP Analysis Reports" were prepared following the review. The first specifically addressed whether the three Alaris production facilities followed the same standard practices and sought to ensure that they were all in compliance with accepted International Organization for Standardization. FE-4 explained the report identified gaps in compliance and uniformity in the three facilities and recommended corrective action.

151. FE-4 stated the second GAP Analysis Report analyzed the gaps in the record-keeping related to problems and modifications made to Alaris pumps. This report was created based on the extent of the missing and lost documentation. FE-4 recalled many instances in which proper documentation simply was not available in order for him to determine what the issue was, or if the appropriate remediation efforts were adopted for each event.

2. Defendants Re-Affirm FY20 Guidance and Continue to Mislead Investors Concerning "Temporary" Delays to Alaris Shipments

152. Suppressing the foregoing adverse facts, Defendants again presented a dramatically different state of affairs to investors on November 21, 2019. On that day, during the Company's presentation to analysts at a Jefferies London Healthcare Conference, Defendants re-affirmed FY20 Guidance reliant on Alaris revenue, reiterating that the temporary shipping delays related to "upgrades" would soon abate.

153. At the conference, a Jefferies LLC analyst asked BD to explain "some of the phasing of expectations on a top line perspective." In response, BD's Senior Vice President, Treasurer, and CFO of BD Medical, John E. Gallagher, stated that:

> As far as Q1 phasing, we did call out Q1 being a 1% to 2% grower. There are a number of dynamics there that are driving it, which effectively create a bit of an imbalance first half, second half. Meaning with a 1% to 2%, we're expecting the first half to be about 4%, ***the back half to be about 6%***.

154. Indeed, Gallagher highlighted Alaris as among a few "key factors" driving performance and emphasized that while Alaris shipments and installations were delayed in the first quarter, BD anticipated "getting all of that back inside of the fiscal year":

> One of the larger ones to call out as well is Alaris pumps. We're ***upgrading*** some software. This is in our MMS business, our infusion pumps. ***We're upgrading some software in the pumps, and that will delay some installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year. So that's what's driving the Q1 being at that 1% to 2%***.

155. Jefferies LLC analyst, Brandon Couillard, probed the FY20 Guidance: "[W]hat parts of the portfolio do you expect to grow faster, slower because -- as you look into '20? What areas do you have the most runway, let's say, for future share gains?" Gallagher responded:

> [W]e've seen very, very strong growth in our Alaris pump business. That -- and although we do see some timing outside of Q1 and into the subsequent quarters of fiscal '20, we posted our strongest ever revenue dollars in the MMS business in the fourth quarter, and ***we expect that momentum to continue when you look at the full year of fiscal '20.***

156. Less than two weeks later, at the Evercore HealthCONx Conference held on December 4, 2019, BD continued to falsely assure investors as to the strength of BD's pump business in 2020. Specifically, when Evercore ISI Institutional Equities analyst, Vijay Muniyappa Kumar, asked, "[h]as anything changed at all in the competitive side for you guys on the pump side," Defendant Reidy replied: "***No. Actually, the pump side, we've been taking 200 points of share last year, and we see that continuing, and we have some visibility to that. So we don't see that being the case.***"

157. Kumar then queried, "I know you had ***revenue deferral*** related to the software chain on the pump side, but that's more of a —," before Defendant Reidy jumped in, assuring: "***That's a timing issue. First half issue, yes***."

158. Even as they minimized the true regulatory overhang and misleadingly talked up BD's growth prospects powered by Alaris revenues, Defendants Forlenza and Polen began cashing in on BD's inflated share price. Indeed, less than two weeks after the Evercore conference, Forlenza and Polen unloaded shares for a staggering $4.3 million and $3.7 million in proceeds, respectively. These unusual sales were not in accord with past practices for these Defendants, as reflected below in Section V.

3. Defendants Misrepresent that Alaris Shipments Have "Fully Resumed" and BD Is "On Track" for FY20 Guidance, Dismissing Investor Concerns Over FDA Action and an Alaris Revenue Hit

159. As Defendants unloaded massive amounts of their BD holdings, they continued to mislead investors about BD's ability to rely on Alaris revenues to meet its ambitious FY20 Guidance.

160. During a JPMorgan Healthcare Conference on January 14, 2020, Defendants reaffirmed the FY20 Guidance and sought to dispel investor concern over BD's discussions with

the FDA—and particularly, whether there would be further delays to Alaris pump shipments and revenue.

161. In response, Defendant Polen proclaimed unequivocally: "***Fully resumed shipping in the first quarter***. So we're back to shipping in Q1 to the majority of our customers."

162. When Polen was later asked if the Alaris situation had "played out as expected," he responded: "***Exactly as expected***."

163. Defendant Polen's representations gave the false impression that the software "upgrades" disclosed on November 5, 2019 had been fully implemented, and the issue—and related discussions with the FDA—was over and done with.

164. Market participants were comforted by Polen's misleading statements about the resumption of Alaris sales, and investment analysts reported Polen's assurances that the Company was on track to meet the FY20 Guidance.

165. In a January 15, 2020 report, a J.P.Morgan analyst stated, "the [first quarter] postponement of Alaris pump shipments [was] also in-line with expectations as the company worked to implement standardized alarm configurations." In a January 14, 2020 research note, Evercore ISI reported: "Most notable was that . . . [Polen] blessed BDX's first quarter guidance and said that the company is on track to meet its full-year guide as well."

166. In truth, Defendants' representations about the quick resumption of Alaris sales, its talks with the FDA, and its FY20 Guidance were materially false or misleading when made. Indeed, as Defendants' subsequent admissions and FE accounts bear out, Alaris suffered from numerous unremediated issues from earlier recalls, other significant software defects and software changes that had not been cleared through the 510(k) Program, and quality systems deficiencies related to Alaris design and modification files the Company was required to maintain. Defendants

also omitted the fact of the FDA's continued active scrutiny of these significant violations, defects, and deficiencies related to Alaris, which had gone on for months.

167. After these misrepresentations, Forlenza again dumped significant amounts of his personal holdings in BD stock. This time, ***he sold over 90,000 shares for proceeds north of a staggering $25 million*** in a series of unusual and suspicious sales over a five-day period from January 23, 2020 to 28, 2020—***just days before the falsity of Defendants' Class Period statements was revealed***.

168. On January 28, 2020, BD held its Annual Shareholders Meeting. During the meeting, Defendant Forlenza again re-affirmed FY20 Guidance and stated:

> And since we just closed the books on our first fiscal quarter, I'm happy to report that we're off to a really solid start for fiscal year 2020. We look forward to providing you with a complete update on our February 6 earnings call, but I'd say that ***our quarter is consistent with the guidance we provided in November, and we are on track for the full year.***

169. Investors' utter lack of awareness of the numerous device and compliance issues imperiling Alaris revenues is reflected in a February 3, 2020 research note by Cowen. In the note, the Cowen analysts looked forward to BD's upcoming February 6, 2020 earnings call for first quarter FY20, and predicted that the Company will achieve the "top-end" of guided revenue growth for the period (5% to 5.5%). Notably, the analysts state, "***mgmt. publicly revealed that discussions with the FDA were completed and Alaris U.S. shipments returned in full during F1Q***."

170. Later in the report, Cowen again noted "[m]anagement's two public disclosures that the Alaris software upgrade was ***completed*** and shipping was ***fully resumed*** in F1Q," remarking that these factors "bode[d] well for the set up relative to expectations and the guidance range."

171. Thus, based on Defendants' consistent representations, the market believed the path had been cleared for the Company to achieve its guided FY20 revenues on the resumed strength of Alaris sales.

4. BD Issues a Voluntary Recall Based on Alaris Software Remediation that Defendants Misleadingly Claim Will Be Fixed Through "Education," "Training," and an Eventual "Software Release"

172. On February 4, 2020, less than forty-eight hours before its first quarter FY20 earnings call, BD issued a recall notification ("February 4 Notification") announcing that it was issuing a "voluntary recall" to address "specific software issues with the BD Alaris™ System Infusion Pumps." The Alaris products affected by the recall included:

- Alaris System PC Unit Model 8000, software versions 9.5 and prior;
- Alaris System PC Unit Model 8015, software versions 9.33 and prior, and software version 12.1.0;
- Alaris Pump Module Model 8100, software versions 9.33 and prior, and software version 12.1.0;
- Alaris Syringe Module Model 8110, software versions 9.33 and prior, and software version 12.1.0; and
- Alaris PCA Module Model 8120, software versions 9.33 and prior, and software version 12.1.0.

173. The February 4 Notification listed five specific software issues including: (i) software errors related to System Error Code 255-XX-XXX; (ii) delay options programming; (iii) low battery alarm failure; (iv) keep vein open (KVO)/end of infusion alarms priority; and (v) use errors related to Custom Concentrating programming.

174. BD stated that it would undertake two actions to address the identified "issues": "comprehensive education and support on the above issues including reference guides and training videos" and "an upcoming software release."

175. The February 4 Notification did not state or indicate that Alaris devices would not be available or suitable for continued use by customers under the voluntary recall. Nor did it state or indicate that any Alaris device would be removed from the market.

176. Nor did the February 4 Notification state or indicate that Alaris devices would be unavailable for purchase or sale, shipment, or installation for any period of time, either under the voluntary recall or otherwise.

177. Indeed, the disclosure cast the recall as addressing technical device issues and related fixes that would have essentially no impact on BD's revenues or financial performance.

178. That same day, BD also sent letters to affected customers about the "voluntary recall." The first, a thirty-three-page letter addressing problems in software versions 9.5 and before identified the following risks that these problems created:

- A software system error that caused the "KVO, End of Infusion" and "End of Infusion" alarms to provide a medium priority alarm rather than a high priority alarm. This defect could cause errors or interruptions in therapy and, as the Company explained, "BD has received two reports of serious injury that are potentially related to this issue."

- A software system error code "255-XX-XXX" which affected alarm and device status indicator lights, and could result in the delay of the start of infusion treatments. BD noted that this software issue had already been the subject of a recall classified as Class II by the FDA in June 2017 and that "BD has received nineteen reports of serious injury that are potentially related to this issue."

- A software system error that impacted the delay infusion feature, which could interrupt therapy. The Company explained that "BD has received sixteen reports of serious injury that are potentially related to this issue."

- A software system error that impacted the low battery alarm and very low battery alarm causing it not to sound, risking interruption of therapy. BD acknowledged that this software issue had already been the subject of a recall and explained it had "received five reports of serious injury that are potentially related to this issue."

- A software system error related to custom concentration programing feature, for which BD stated it had "received one report of death and thirteen reports of serious injury that are potentially related to this issue."

179. The second letter, related to devices with software version 12.1.0, detailed four of the above issues and the affected Alaris modules and model numbers.

180. According to BD, the letters aimed to "provide[] important user actions to help mitigate the potential risks until these software issues have been remediated." Critically, however, the letters stated the Company has "***determined that affected products can continue to be used***" in accordance with information in the letter and device user manual."

181. The letters further disclosed that the FDA had been informed of the voluntary recall. In addition, BD stated that it had been in discussions with FDA prior to February 4, 2020 about the "upcoming software version" that was intended to eventually remediate the five identified Alaris software issues.

182. Consistent with the February 4 Notification, the letters did not state or indicate that Alaris devices would be unavailable for purchase or sale, shipment, or installation for any period of time, nor did they indicate that the FDA had taken or signaled the potential for any adverse action against BD with respect to Alaris. As a result, the Company's stock price remained artificially inflated on February 4 and 5, 2020.

183. Ultimately, on March 6, 2020, several weeks after the Class Period had ended, the FDA published a notice classifying BD's "voluntary recall" as a Class I recall, the most serious type.

5. Defendants Finally Reveal the Truth

184. Defendants' fraud was ultimately corrected by their disclosures to the market on February 6, 2020. These corrective disclosures came through information provided in a Company Form 8-K with an attached earnings press release ("Earnings Release"), and shortly thereafter, on an 8:00 a.m. Eastern Time conference call regarding BD's first quarter FY20 earnings.

185. In the Earnings Release, BD announced:

> [BD] is continuing to work with the U.S. Federal Drug Administration (FDA) on its software remediation plan for the Alaris System, which will require additional regulatory filings beyond what the company previously anticipated. The company expects to submit its comprehensive regulatory filing in the fourth quarter of fiscal year 2020. In the interim, the company will partner with the FDA and existing customers to ensure continued access to the Alaris System under medical necessity. As a result, the company is lowering its full fiscal year revenue and adjusted diluted earnings per share guidance.

186. The Earnings Release further revealed that BD "is lowering its full fiscal year 2020 revenue and adjusted diluted earnings per share guidance to reflect the impact of the remediation effort and anticipated loss of sales of the Alaris infusion system." The Company stated, as opposed to its prior guidance of 5% to 5.5% growth, that it now expected "full fiscal year 2020 revenues to increase 1.5 to 2.5 percent as reported, or 2.5 to 3.5 percent on a currency-neutral basis."

187. Within approximately an hour, on the earnings call, Defendant Polen further explained to stunned investment analysts that: (i) Alaris would be pulled from the market due to software, device, and related quality systems issues; (ii) the FDA was requiring BD to submit a new 510(k) application related to numerous historical software changes before resuming Alaris sales; and (iii) as a consequence, the negative revenue impact to BD in FY020 would be roughly $400 million.

188. These disclosures revealed to the market fully, for the first time, both the significant product and regulatory compliance issues that had plagued Alaris and the unrelenting FDA scrutiny on Alaris that BD had misleadingly downplayed throughout the Class Period.

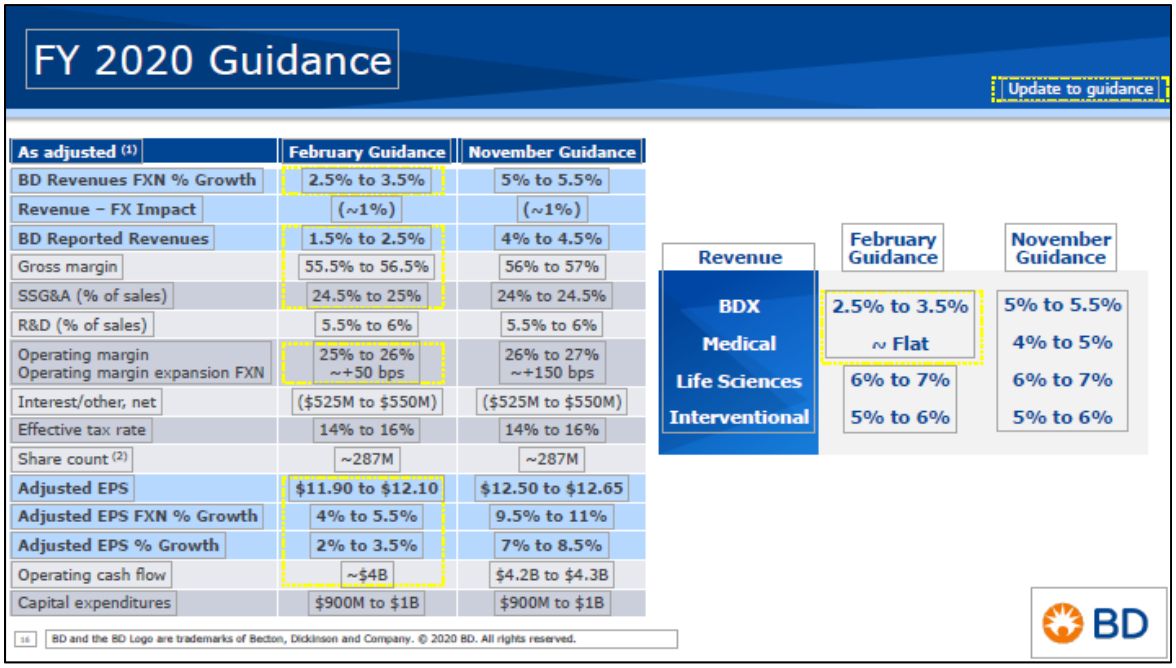
189. These facts—previously unknown to investors—reflected that BD's FY20 Alaris revenues had been in severe jeopardy for months, and that Defendants' FY20 Guidance and statements concerning Alaris sales had been materially false or misleading.

190. Specifically, as to regulatory and remediation issues regarding Alaris and BD's quality system, Polen stated in one colloquy:

> In November, we told you we were planning to make some improvements to our Alaris pump software, including upgrades to alarm prioritization and optimization. We indicated then that we were in active discussions with the FDA about the timing and implementation of these improvements. Relying on our quality process within the Infusion business and how we've managed Alaris software updates over time, the team believed we could take a phased approach to releasing Alaris software updates and that these releases did not require a 510(k) clearance. We then issued the first phase of our software updates in December, and we resumed shipping, as we shared with you last month.
>
> Through our ongoing dialogue with the FDA, including in-depth discussion this past Monday, we learned that the FDA disagreed with our conclusion about the need for a new 510(k) clearance for these software upgrades. And in light of the consent decree, the FDA has requested that we combine all Alaris software enhancements, recall remediation updates and changes made to the Alaris system over time into a single comprehensive 510(k) filing, which we're going to submit in the fourth quarter of FY '20. We're actively continuing to collaborate with the FDA to ensure we meet their expectations for this upcoming regulatory submission.
>
> I want to be clear here that while we relied on our infusion quality process and system, we have now learned that in this case, it did not meet FDA's expectations, and we're committed to taking the appropriate actions to get this right.

191. Insofar as this and similar Company disclosures on February 6, 2020 assert that Defendants were unaware of the extent of the Alaris-related issues before talking with the FDA on February 3, 2020, such excuses are implausible and misleading attempts at damage control (on the basis of, among other things, the multiple un-remediated Alaris issues, unapproved software changes, related quality systems deficiencies, and ongoing FDA scrutiny) as evidenced by other statements made by Defendants within the same conference call.

192. In addition, with respect to financial performance, Defendant Polen disclosed that, as a direct result of the Alaris "situation," BD had drastically cut the FY20 Guidance which Defendants had reaffirmed numerous times between November 2019 and January 2020. Specifically, Polen disclosed that "based on this situation, we reduced our guidance range by approximately $400 million in revenue and $0.60 in EPS for fiscal year '20," as reflected on a slide BD presented in conjunction with the earnings call:



193. Defendant Reidy similarly stated that:

> [W]e are revising our revenue growth guidance to 2.5% to 3.5%, specifically due to the Alaris situation. Our updated range reflects several scenarios based on our ongoing conversations with the FDA, with the bottom end of our range assuming a very limited ability to ship Alaris pumps this fiscal year. By segment, for the full year, we now expect BD Medical revenue growth to be about flat.

194. Reidy's admission that the new, revised financial analyses and guidance BD disclosed early in the morning of February 6, 2020, "reflects several scenarios based on our ongoing conversations with the FDA" underscores Defendants' prior misrepresentations about those same conversations.

195. After investment analysts sought more detail, Defendant Polen confirmed on the call that "the $400 million, that is essentially is pump capital that we're unable to ship." Reidy echoed: "***So you can think about the takedown as entirely the Alaris pump issue.***"

196. Several analysts pressed Defendants for more information on the news. A William Blair & Company L.L.C. analyst asked about BD's Alaris-related quality systems:

> It seems like some of these software upgrades were kind of already done and you got to kind of repackage them. And then I just want to dig into what specifically

> did the FDA come in and say that they didn't like about your quality systems? I mean what changes do you think you need to make more broadly on the quality system side?

197. In response, Defendant Polen provided further detail concerning BD's Alaris-related quality systems and FDA's "ongoing dialogue" with BD regarding the same:

> So as I mentioned, based on the quality system in our Infusion business, we've made software upgrades over time to the Alaris system. And ***over that period of time, we're talking -- not this year, we're talking a number of years, our quality process determined that those upgrades that we've been making in that business did not require a 510(k) clearance. And so most recently, on the most recent changes and updates that we made, we followed that same process. And our team determined based on that process that those recent updates in November also did not require a new 510(k) clearance***. And so we released that software improvement in December, and we resumed shipping, as we had shared with you last month.
>
> Since what we've learned, and as I mentioned, ***we had a key meeting with the FDA as recently as this Monday, through our ongoing dialogue with the FDA***, we learned that ***the FDA disagreed with that determination about the need for a new 510(k) clearance for the updated software. And that applies not just to the upgraded software that we're talking about in November, but that decision process that had occurred over time.*** And so as I said, we're collaborating with the FDA on their request to combine all the Alaris software enhancements and remediation upgrades with the additional changes made to the Alaris system over time, right, over years, into a more comprehensive regulatory filing, which is going to be submitted this summer. And so while you're right, we are ready to -- we have the information ready for the recent software upgrades, we are -- ***the work that has to take place between now and the submission date is more in reference to the historical changes that have been made over multiple years going back, and the -- some additional testing that we need to do on those historic changes to reflect the testing requirements today. So that's the work that has to be done***.

198. In response, an analyst from Bank of America Merrill Lynch questioned how Defendants purportedly were blindsided by the FDA's actions, stating: "I'm struggling to understand kind of how you got caught offguard and how this went from sort of a software upgrade to something much more significant."

199. Polen responded:

> [I]t's not unprecedented where there are situations where over time a product evolves. And then the FDA looks and says, wait a minute, your current 510(k) needs to be updated to reflect those series of changes over time. ***And in this case, we had***

> ***a -- there is a process in the business, and there's a specific quality process within the Infusion business within the consent decree that the team was following that said each of those individual changes didn't require a 510(k) process.*** Again, when the FDA looks back at it over a 5-, 10-year period, they say, wait a minute, you actually need to put in a 510(k) given that series of changes that have been made. And that's the exact work that we're doing.

200. Of course, this scenario of cumulative device changes over time requiring a 510(k) clearance was specifically addressed by the FDA 510(k) guidance published several years earlier, as noted above, and previously raised internally by BD's Regulatory Department, as corroborated by Former Employees.

201. In response to the disclosure of corrective information on the earnings call and in the Earnings Release, BD's stock price cratered, dropping $33.74 (nearly 12%) in one day on unusually heavy trading volume to close at $252.25 on February 6, 2020. The drop eliminated approximately $10 billion in market capitalization and shareholder value.

202. Investment analyst reports and market commentary recognized the direct relationship between the new corrective information and the massive BD stock price decline on February 6, 2020.

203. For example, a report by CFRA issued upon the issuance of the Earnings Release on February 6, 2020 stated: "Shares of BDX declined 10% in pre-market trading on the unexpected announcement that BDX is working with the FDA on a software remediation plan for the Alaris pump system."

204. Similarly, a report by investment analysts at Wells Fargo that same day noted BD's "unexpected delay in its Alaris pump remediation effort," reporting:

> Management lowered its FY20 revenue growth guidance from 5-5.5% to 2.5-3.5% ex-FX growth, primarily reflecting ~$400MM reduction in pump sales expectation. The EPS guidance is also reduced from $12.50-$12.65 to $11.90-$12.10. Management expects to file the 510K for the Alaris pump in FQ4, although we see a risk of delay into FY21. Bottom-line, we expect the pump issue to remain an overhang given the uncertainty around timing of return to market. That being said,

> BDX shares are down 11.8% today (vs. S&P 500 +0.3%) with the market cap shrinking by about $10B, suggesting that the market is likely discounting more than just $400MM of potential permanent revenue loss.

205. The Wells Fargo report elaborated:

> Key risk is a delay in Alaris pump's return. Admittedly, there is a lot of uncertainty around timing of Alaris getting back to the market and the risk of a delay is real in our view. While the company is targeting FQ4 filing, we believe BDX may be in relatively early stage of compiling historical software update data from previous years and thus the submission timeline could slip into FY21. Additionally, with a somewhat checkered history (multiple recalls) for Alaris and the pump industry, we believe that FDA review timeline could extend beyond the 6 months. Additional delay in Alaris' return to market could translate to additional lost sales in FY21 and may lead to greater permanent share loss.

6. Post-Class Period Developments

206. Events following the close of the Class Period further reveal the nature and extent of BD's compliance violations and Alaris product issues.

207. On March 6, 2020, the FDA slapped BD's February 4, 2020 "voluntary" recall with a Class I recall designation—the most serious type of recall reserved for situations where use of the devices may cause serious injuries or death—and reported that the recall covered over 750,000 Alaris devices.

208. Defendant Polen subsequently addressed BD's efforts to remediate the issues disclosed on February 6, 2020 on earnings calls and investor conferences.

209. On May 7, 2020, Polen told investors during the Company's earnings call for the second quarter that his "executive team is directly engaged on this on a daily and weekly basis" and it is "the critical priority for the company."

210. On June 10, 2020, Polen stated during the William Blair 40th Annual Virtual Growth Stock Conference that "[w]e've [BD] got over 150 people now working full time on that [referring to the 510(k) submission]."

211. On August 6, 2020, Polen stated during the Company's earnings call for the third quarter that after a "tremendous amount of work" BD had just now—six months since it revealed the truth in February 2020–"completed a retroactive risk assessment on . . . ever[y] change that's been made to the Alaris system since the initial 510(k)."

V. ADDITIONAL ALLEGATIONS OF SCIENTER

212. In addition to the facts discussed above, the following facts further support a strong inference that Defendants knowingly or recklessly made false or misleading statements to investors during the Class Period:

213. ***First***, Defendants Forlenza and Polen were financially motivated to commit securities fraud, as their fraud allowed them to sell BD common stock at artificially inflated prices. In fact, these Defendants realized millions of dollars in inflated stock sales during the Class Period that were suspicious in amount and timing, as detailed below:

Insider	Date	Shares Sold	Weighted Avg. Price[6]	Total Proceeds
Forlenza	12/12/2019	4,717	$265.57	$1,252,693.69
Forlenza	12/12/2019	11,626	$265.57	$3,087,516.82
Forlenza	1/2/2020	33,365	$271.28	$9,051,257.20
Forlenza	1/2/2020	12,083	$271.28	$3,277,876.24
Forlenza	1/8/2020	13,860	$275.19	$3,814,133.40
Forlenza	1/8/2020	4,923	$275.19	$1,354,760.37
Forlenza	1/10/2020	19,675	$275.15	$5,413,576.25
Forlenza	1/10/2020	6,990	$275.15	$1,923,298.50
Forlenza	1/23/2020	6,284	$280.06	$1,759,897.04
Forlenza	1/23/2020	2,180	$280.06	$610,530.80
Forlenza	1/24/2020	7,177	$280.13	$2,010,493.01
Forlenza	1/24/2020	2,489	$280.13	$697,243.57
Forlenza	1/27/2020	25,546	$280.09	$7,155,179.14
Forlenza	1/27/2020	8,860	$280.09	$2,481,597.40
Forlenza	1/28/2020	9,848	$280.96	$2,766,894.08
Forlenza	1/28/2020	28,514	$280.96	$8,011,293.44

[6] This number is the weighted average price per share reflected in the Forms 4.

Insider	Date	Shares Sold	Weighted Avg. Price[6]	Total Proceeds
Polen	12/16/2019	1,953	$269.63	$526,587.39
Polen	12/16/2019	5,568	$269.63	$1,501,299.84
Polen	12/16/2019	1,954	$269.63	$526,857.02
Polen	12/16/2019	4,432	$269.63	$1,195,000.16
Total		**212,044**		**$58,417,985.36**

214. ***Defendant Forlenza*** sold a total of 198,137 shares of BD common stock throughout the three-month Class Period for total proceeds of ***$54,668,240.95***. These sales were suspicious in amount—in the three-month (93-day) Class Period, Forlenza sold ***four times more*** BD common stock than he sold during the same three-month period the year before (November 5, 2018 to February 5, 2019) and ***twelve times more*** than in the three-month (93-day) period that immediately preceded the Class Period. In fact, Forlenza's sales in the three-month Class Period alone were ***four times*** his sales for the entire calendar year of 2018.

215. The timing of Forlenza's sales was likewise suspicious, as they were clustered: (i) around and after dates on which he is alleged to have made material misrepresentations to investors, which caused or maintained artificial inflation in BD's common stock; and (ii) during the period immediately preceding Defendants' disclosures on February 6, 2020, after which the artificial inflation was removed from BD's share price. Indeed, just nine days prior to Defendants' revelation, ***he sold over 90,000 shares for total proceeds of over $25 million*** in a series of stock dumps between January 23, 2020 and January 28, 2020. Further, nearly all of Forlenza's sales were made pursuant to a 10b5-1 trading plan that he entered into on December 16, 2019—***during the Class Period and while in possession of material, non-public information.***

216. Notably, to sell the large amount of common stock Forlenza sold during the Class Period, he exercised stock appreciation rights that were at no risk of expiration—the majority of

these rights were not set to expire until November 22, 2021 and small minority (16,343 shares) were to expire on November 23, 2020.

217. ***Defendant Polen*** sold a total of 13,907 shares of BD common stock on or about December 16, 2019 at an average weighted price of $269.63, for total proceeds of $3,749,744.41. Polen's sales were suspicious in amount—his sales exceeded those he made in the three-month (93-day) period directly preceding the Class Period and during the same three-month period the year before (November 5, 2018 to February 5, 2019)—the latter by 18% .

218. Polen's sales followed dates on which he is alleged to have made material misrepresentations to investors, which caused or maintained artificial inflation in BD's common stock. Moreover, the sales followed a significant, sustained increase in BD's common stock price following Defendants' false or misleading issuance and reaffirmation of FY20 Guidance.

219. Like Forlenza, Polen exercised stock appreciation rights that were at no risk of expiration. The majority of the rights Polen exercised to make his large Class Period sales were not set to expire until November 26, 2025 and small minority (3,907 shares) were to expire on November 25, 2024.

220. ***Second***, the alleged fraud concerned BD's core segment, BD Medical, and key product suite, Alaris. As discussed above, the Medical segment made up over half of BD's total annual revenue in 2017, 2018, and 2019. BD reported in SEC filings prior to and during the Class Period that BD Medical's underlying revenue growth was "driven" by the "[MMS] unit's installation of dispensing and infusion systems." Alaris was throughout the Class Period the MMS unit's largest and most important product line and was routinely identified by the Company as BD's "[k]ey" product line, including because it served as the linchpin to the Company's "interoperability" strategy.

221. Moreover, Defendants repeatedly spoke about and focused investors on Alaris and identified its attendant revenue as the driving force behind BD's FY20 Guidance. Defendants' public statements strongly and plausibly suggest that each had detailed knowledge of or access to the material facts and information misrepresented or concealed by Defendants; alternatively, Defendants were reckless in failing to investigate the subject about which they spoke. Indeed, their public statements demonstrate that each was knowledgeable about and actively involved in—among other things: (i) reviewing, analyzing, and approving BD's FY20 Guidance; (ii) formulating and overseeing BD's strategy and business with respect to Alaris; (iii) overseeing the status of purported software "updates" and "improvements" to Alaris products; (iv) assessing the impact of Alaris-related revenue on BD's overall performance; and (v) participating in and guiding the Company's interactions with the FDA concerning Alaris. Moreover, Defendant Polen led the CareFusion acquisition as segment president of BD Medical and, thus, was acutely aware both of the 510(k) regulatory framework applicable to Alaris and the Amended Consent Decree by which BD was legally bound for its Alaris products. That Defendants made many of these public statements in response to direct questions about Alaris from investment analysts only further supports a strong inference of scienter.

222. The clear and undeniable importance of Alaris to BD's financial performance and FY20 Guidance is further confirmed by the fact that the drastic cut to FY20 Guidance and, namely, expected revenue, resulted from the Company's inability to ship and sell Alaris products, as Defendants explicitly told investors on February 6, 2020.

223. These facts collectively raises a strong inference that the Individual Defendants either knew, or were reckless in disregarding that their alleged misstatements were materially false or misleading when made.

224. ***Third***, as BD's senior-most executives, the Individual Defendants controlled the contents of the Company's public statements, including the FY20 Guidance, and had access to material, adverse, nonpublic information about Alaris, BD's failure to comply with the FDA's 510(k) clearance requirement and other federal regulations, the litany of defects and other problems afflicting the Alaris line, and the FDA's ongoing scrutiny of the same. These Defendants, because of their high-ranking positions and direct involvement in the everyday business of the Company, directly participated in the management of BD's operations, possessed and exercised the power and authority to control the contents of the Company's SEC filings, press releases, and other market communications, and were privy to confidential information concerning BD and its business, operations and financial statements, and strategy.

225. The Individual Defendants were directly involved in controlling the content of, and in drafting, reviewing, publishing, and/or disseminating, the false or misleading statements alleged herein; were aware or recklessly disregarded that the false or misleading statements and omissions were being issued; and approved or ratified these false or misleading misstatements and omissions, all in violation of the federal securities laws. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the contrary representations being made were then materially false or misleading. The Individual Defendants are thus liable for the false statements and omissions pleaded herein under the Exchange Act. Further, as BD's senior-most officers, the Individual Defendants' knowledge or recklessness is imputed to the Company.

226. ***Fourth***, the temporal proximity and sharp contrast between Defendants' false or misleading statements during the Class Period and BD's disclosures on February 6, 2020, further

support a strong inference of scienter. Indeed, just three months after issuing positive and optimistic FY20 Guidance and proclaiming to investors that Alaris revenue would drive BD's performance, and ***just nine days after re-affirming that FY20 Guidance yet again***, BD shocked the market by drastically slashing Guidance because Alaris shipments would be required to stop indefinitely while BD pursued 510(k) clearance for the multiple changes that BD had implemented to Alaris without FDA approval.

VI. DEFENDANTS' MATERIALLY FALSE OR MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACT

A. November 5, 2019 - Press Release, Earnings Call, and Presentations

227. On November 5, 2019, BD issued a press release on Form 8-K announcing its financial results for the Company's fourth quarter and full FY19 ending September 30, 2019, and providing fiscal 2020 guidance (i.e., the FY20 Guidance).

228. In that press release, BD represented to investors that "***the [C]ompany expects full fiscal year 2020 revenues to increase 4.0 to 4.5 percent as reported, or 5.0 to 5.5 percent on a currency-neutral basis***" and ***"[a]s adjusted, the company expects full fiscal year 2020 diluted earnings per share to be between $12.50 and $12.65, resulting in growth of approximately 9.5 to 11.0 percent on a currency-neutral basis***."

229. The same day, November 5, 2019, BD held an earnings call to discuss the Company's fourth quarter, FY19 results and FY20 Guidance. Defendants Forlenza, Reidy, and Polen participated and spoke on behalf of the Company and led investors through an investor presentation entitled "Fourth Quarter and Full Year Results Fiscal Year 2019" and a summary graphic entitled "Q4 & FY19 Financial results," both of which were published to BD's website.

230. The presentation included the following slides reflecting ***BD's FY20 Guidance***, which Defendants discussed and presented during the call:

FY 2020 Guidance and outlook

FY 2020 Guidance	
Revenues FXN % Growth	5.0% to 5.5%
Adjusted EPS $	$12.50 to $12.65
Underlying EPS FXN % Growth	15.5% to 17%
Adjusted EPS FXN % Growth	9.5% to 11%
Adjusted EPS % Growth	7% to 8.5%

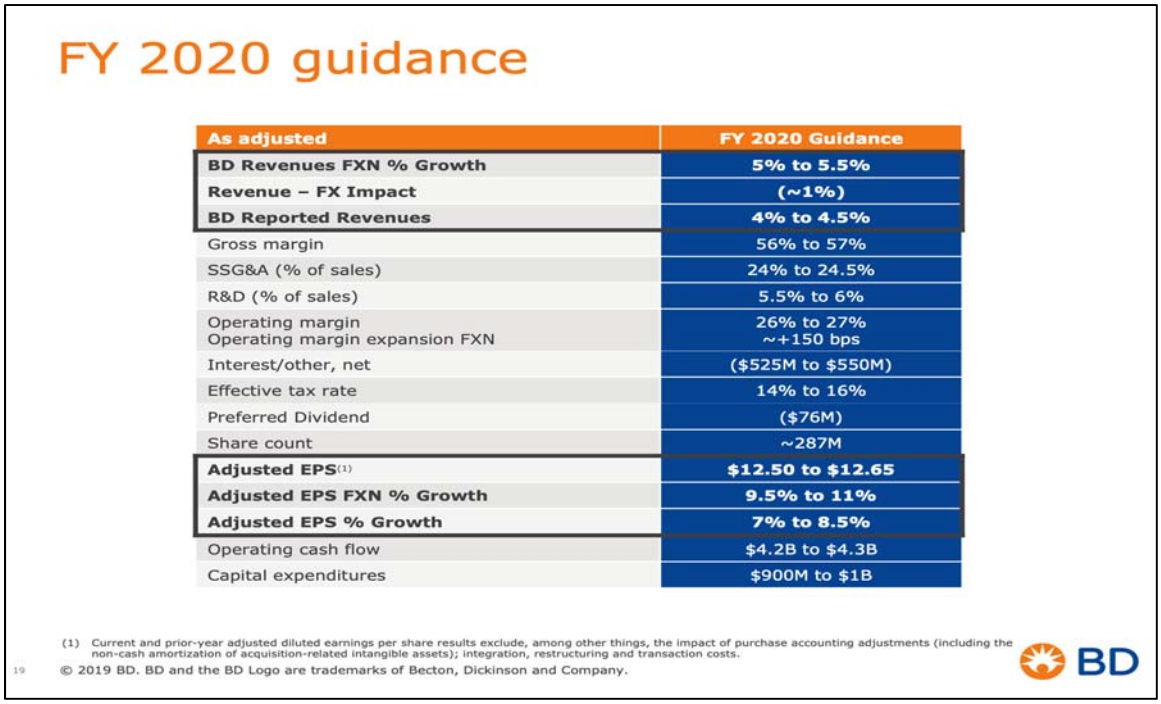
- Guidance reflects strong revenue growth and continued momentum
- Revenue growth coupled with margin expansion driving high-teens underlying EPS growth
- Confident in our outlook for FY 2020
- **BD Analyst Day 2020 set for May 28, 2020 in New York**

BD

FY 2020 revenue guidance

Revenues FXN % Growth Guidance	FY 2020 Guidance
BDX	5% to 5.5%
Medical	4% to 5%
Life Sciences	6% to 7%
Interventional	5% to 6%

BD



FY 2020 guidance

As adjusted	FY 2020 Guidance
BD Revenues FXN % Growth	**5% to 5.5%**
Revenue – FX Impact	**(~1%)**
BD Reported Revenues	**4% to 4.5%**
Gross margin	56% to 57%
SSG&A (% of sales)	24% to 24.5%
R&D (% of sales)	5.5% to 6%
Operating margin Operating margin expansion FXN	26% to 27% ~+150 bps
Interest/other, net	($525M to $550M)
Effective tax rate	14% to 16%
Preferred Dividend	($76M)
Share count	~287M
Adjusted EPS(1)	**$12.50 to $12.65**
Adjusted EPS FXN % Growth	**9.5% to 11%**
Adjusted EPS % Growth	**7% to 8.5%**
Operating cash flow	$4.2B to $4.3B
Capital expenditures	$900M to $1B

(1) Current and prior-year adjusted diluted earnings per share results exclude, among other things, the impact of purchase accounting adjustments (including the non-cash amortization of acquisition-related intangible assets); integration, restructuring and transaction costs.

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231. At the outset of the call, Defendant Forlenza presented BD's FY20 Guidance, directing investors to slide 6 of the presentation and stating:

> ***[Y]ou will see our initial guidance for fiscal year 2020, which reflects continued momentum across our businesses and strong revenue growth of 5% to 5.5%. On the bottom line, we expect to deliver adjusted EPS between $12.50 and $12.65***. This represents currency-neutral growth of 9.5% to 11% that is driven by strong underlying growth that is breaching high teens. ***All in all, we expect to drive earnings growth of about 7% to 8.5%***. Our outlook is based on our current view of the environment.

232. Defendant Reidy echoed Forlenza's statements concerning BD's FY20 Guidance, stating: "Moving on to Slide 17 [of the presentation] and our full fiscal year 2020 revenue guidance. ***We expect currency-neutral revenue growth of 5% to 5.5% on a comparable basis***." Reidy further declared that "***[b]y segment, for the full year, we expect BD Medical revenues to grow between 4% and 5%***."

233. While discussing BD's fourth quarter results and performance, Defendant Reidy specifically identified the "ongoing momentum and share gains in [MMS]" as a key driver for fourth quarter FY19 performance, stating: "BD Medical revenues grew 5.3% in the fourth quarter

and 5.1% for the full fiscal year. As expected, fourth quarter performance in the Medical segment was ***driven by ongoing momentum and share gains in Medication Management Solutions*** and continued strength in Pharmaceutical Systems."

234. Defendant Reidy also claimed BD was planning certain "improvements" and "upgrades" to Alaris and in discussions with the FDA about the "timing of implementations of these upgrades," assuring investors, however, that any such move would do nothing more but shift Alaris revenue from first half FY20 to "the balance of the fiscal year":

> ***From a phasing perspective, we expect revenue growth in the first half of the fiscal year to be approximately 100 basis points below the full year guidance range driven by first quarter revenue growth of 1% to 2%. In our MMS business, we are planning to make some improvements to our Alaris pump software, including upgrades to alarm prioritization and optimization. We are in discussions with the FDA about the timing of implementation of these upgrades and the possibility of bundling them with a new software version release. This is expected to move the timing of some sales from Q1 to the balance of the fiscal year***.

235. Evercore ISI analyst, Vijay Muniyappa Kumar, pressed Defendants for more information concerning the purported Alaris pump upgrades and their impact, if any, on the Company's expected FY20 revenue growth, asking:

> I guess the Q1 impact on MMS, I think you mentioned software changes and I think your main competitor is talking about a rollout of a new platform. Can you maybe just talk about the comparative dynamics and whether the software rollout, whether that's just a fourth quarter phenomena? Or usually, when I hear software, I think about integration issues. So just maybe give some color on what's changing there.

236. Defendant Reidy replied: "We did say that we expect revenue growth to be between 1% and 2%, ***and one of the drivers of that is the timing of the upgrades on the Alaris pump software***." Reidy further stated: "Having said that, despite the 1% to 2% growth in the first quarter, ***we expect the first half to be relatively close to guidance of within 100 basis points***. So you kind of have a similar split between first half and second half that you had in '19 driven by a number of those factors."

237. Defendant Polen likewise touted Alaris as the "clear leader and product choice" in MMS for BD:

> So just a note. As you know, Alaris is the clear leader and product choice in, not only the infusion market, but also as part of a broader Medication Management Solution that our customers are investing in. ***And it's part of our process and our strategy in the business to continually iterate and make enhancements to the platform. And so you've seen us do that certainly on the hardware side with significant investments, such as the new Alaris M2 pump launch, which has been extremely well received by our customers. And we've been making those same type of investments in software upgrades over the last couple of years. And this upgrade right here is a continued reflection on those investments and will be forthcoming***.
>
> I would just say in terms of momentum, maybe just one other comment there on your question, we saw in FY '19 near or at, I'd say, record levels of continued share gain both in the infusion and the dispensing business, so about 200 basis points of gain in infusion and 100 in dispensing. ***And we see no slowdown in that momentum.***

238. Defendants' bolded statements identified in paragraphs 234 and 236-37 that BD had implemented the temporary pause on Alaris shipments in the first quarter to provide beneficial "upgrades," "improvements," and "enhancements" to Alaris were materially false or misleading when made. As Defendants' subsequent admissions and FE accounts bear out, at the time of these misrepresentations, Alaris suffered from numerous, significant software defects and BD was marketing Alaris products that included software changes made over a five-year period that had not been cleared through the mandatory FDA 510(k) process. *See, e.g.*, ¶¶ 84-85, 88-89, 120-42. In fact, those problems posed significant safety issues to patients and signaled major compliance failures that were the subject of ongoing FDA scrutiny, and hindered BD's ability to generate the Alaris revenue that Defendants repeatedly told investors supported its FY20 Guidance. Indeed, unbeknownst to investors, Alaris shipments had already been put on-hold following an FDA audit prior to the Class Period in response to those very defects and failures. *See, e.g.*, ¶¶ 134-36.

239. Defendants' bolded statements identified in paragraphs 234, 236, and 237 downplaying and mischaracterizing their ongoing discussions with the FDA as a perfunctory question of timing—i.e., ***when*** the FDA would greenlight new, software upgrades—and representing that the pause in Alaris shipments was a fleeting, several-week delay with no impact on FY20 Alaris sales and revenue were materially false or misleading when made for the reasons set forth in paragraph 238. These representations were also misleading because BD's quality systems and controls as to Alaris were not in compliance with FDA requirements and because BD was out of compliance with its obligations under the Amended Consent Decree, further jeopardizing Alaris revenue and belying Defendants' assurances to investors that Alaris sales would return and drive BD to achieve its FY20 Guidance. *See, e.g.*, ¶¶ 143-51.

240. Defendants' bolded statements identified in paragraphs 231-34 and 236-37 that BD's performance was and would continue to be driven by "***ongoing momentum and share gains in Medication Management Solutions***" and that "***we see no slowdown in that momentum***" for Alaris were materially false or misleading when made for the reasons set forth in paragraphs 238 and 239.

241. In light of the facts set forth in paragraphs 238-40, Defendants issued financial guidance (i.e., FY20 Guidance), set forth in paragraphs 228 and 230-32 that lacked a reasonable basis in fact because it did not take into account the foregoing undisclosed adverse facts, thereby misrepresenting BD's true financial condition and growth prospects, which Defendants represented were anchored by Alaris revenue and Alaris's "interoperability" with other BD products. Such financial guidance was also misleading because, at the time it was issued, Defendants did not disclose specific, material information which, had it been disclosed, would have reasonably called into doubt BD's financial guidance. Having elected to issue financial

guidance, Defendants violated their duties to: (i) disclose such specific information so as to render BD's financial guidance not misleading; and (ii) update BD's financial guidance when Defendants became aware of such information.

B. November 21, 2019 - Jefferies London Healthcare Conference

242. On November 21, 2019, John E. Gallagher, BD's Senior Vice President, Treasurer, and CFO of BD Medical, attended, presented, and spoke on behalf of BD at the Jefferies London Healthcare Conference.

243. At the conference, Brandon Couillard, a Jefferies LLC analyst, asked Gallagher to explain "some of the phasing of expectations on a top line perspective."

244. Gallagher responded, "[a]s far as Q1 phasing, we did call out Q1 being a 1% to 2% grower. There are a number of dynamics there that are driving it, which effectively create a bit of an imbalance first half, second half. Meaning with a 1% to 2%, we're expecting the first half to be about 4%, ***the back half to be about 6%***."

245. Couillard then asked Gallagher what factor or factors drove the Company's FY20 Guidance:

> If you look at the sort of the guidance that you established for '20 just recently on the fourth quarter call a few weeks ago, kind of talked about 5% to 5.5% organic growth on top line. Can you walk us through some of the factors that you've kind of contemplated some of the puts and takes? You also mentioned kind of 1% to 2% organic growth, I think, in the first quarter of the year. ***So just kind of help us with some of the phasing of expectations on a top line perspective, and then I would like to touch on bottom line as well.***

246. Gallagher sought to allay any concerns over a delay in installments or shipments of Alaris products during FY20:

> ***[P]robably one of the larger ones to call out as well is Alaris pumps. We're upgrading some software. This is in our MMS business, our infusion pumps. We're upgrading some software in the pumps, and that will delay some installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year***.

247. Couillard further asked, "what parts of the portfolio do you expect to grow faster, slower because -- as you look into '20? What areas do you have the most runway, let's say, for future share gains?"

248. Gallagher responded:

> ***Of course, the other one is in our MMS business, where we've seen very, very strong growth in our Alaris pump business. That -- and although we do see some timing outside of Q1 and into the subsequent quarters of fiscal '20, we posted our strongest ever revenue dollars in the MMS business in the fourth quarter, and we expect that momentum to continue when you look at the full year of fiscal '20***. So those are a couple of highlights that I'd mention within Medical.

249. Defendant BD's bolded statements identified in paragraphs 244, 246, and 248 were materially false or misleading when made for the reasons set forth in paragraphs 238-41.

C. November 27, 2019 - FY19 Form 10-K

250. On November 27, 2019, the Company filed its FY19 Form 10-K for the period ending September 30, 2019, which was approved, signed and certified by Defendants Forlenza and Reidy.

251. Defendants BD, Forlenza, and Reidy represented in the FY19 Form 10-K the following about the FDA's regulations and expectations:

> ***Our failure to comply with the applicable good manufacturing practices, adverse event reporting, and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, warning letters or consent decrees, closure of manufacturing sites, import bans, seizures or recalls of products and damage to our reputation***. More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk.

252. Defendants BD, Forlenza, and Reidy also represented in the FY19 Form 10-K the following about the Amended Consent Decree and BD's obligations thereunder:

> ***While this BD organizational unit remains subject to the amended consent decree, which includes the requirements of the original consent decree, it has made substantial progress in its compliance efforts***. However, we cannot predict

> the outcome of this matter, and the amended consent decree authorizes the FDA, in the event of any violations in the future, to order us to cease manufacturing and distributing infusion pumps, recall products and take other actions. . . .
>
> We also cannot currently predict whether additional monetary investment will be incurred to resolve this matter or the matter's ultimate impact on our business. ***We may be obligated to pay more costs in the future because, among other things, the FDA may determine that we are not fully compliant with the amended consent decree and therefore impose penalties under the amended consent decree***, and/or we may be subject to future proceedings and litigation relating to the matters addressed in the amended consent decree. ***As of September 30, 2019, we do not believe that a loss is probable in connection with the amended consent decree,*** and accordingly, we have no accruals associated with compliance with the amended consent decree.

253. Defendants BD, Forlenza, and Reidy further stated in the FY19 Form 10-K:

> As a result of the CareFusion acquisition, we are operating under a consent decree with the FDA relating to our U.S. infusion pump business. ***The consent decree authorizes the FDA, in the event of any violations in the future, to order us to cease manufacturing and distributing products, recall products or take other actions, and we may be required to pay significant monetary damages if we fail to comply with any provision of the consent decree.***

254. Relatedly, Defendants BD, Forlenza, and Reidy represented in the FY19 Form 10-K that "[d]elays in obtaining necessary approvals or clearances from the FDA or other regulatory agencies or changes in the regulatory process may also delay product launches and increase development costs" and that:

> The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. ***These events could lead to recalls or safety alerts relating to our products (either voluntary or as required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market***. A recall could result in significant costs and lost sales and customers, enforcement actions and/or investigations by state and federal governments or other enforcement bodies, as well as negative publicity and damage to our reputation that could reduce future demand for our products. Personal injuries relating to the use of our products can also result in significant product liability claims being brought against us. ***In some circumstances, such adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements***.

255. Defendants BD, Forlenza, and Reidy likewise focused investors' attention on BD's purportedly robust and adequate quality systems, stating in the FY19 Form 10-K:

> ***BD actively maintains FDA/ISO Quality Systems that establish standards for its product design, manufacturing, and distribution processes. Prior to marketing or selling most of its products, BD must secure approval from the FDA and counterpart non-U.S. regulatory agencies***. Following the introduction of a product, these agencies engage in periodic reviews and inspections of BD's quality systems, as well as product performance and advertising and promotional materials. These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. ***Where possible, BD anticipates these factors in its product development and planning processes. These agencies possess the authority to take various administrative and legal actions against BD, such as product recalls, product seizures and other civil and criminal sanctions***. BD also undertakes voluntary compliance actions, such as voluntary recalls.

256. Defendants BD's, Forlenza's and Reidy's bolded statements identified in paragraphs 251-55 were materially false or misleading when made for the reasons set forth in paragraphs 238-40 and because they characterized as contingent or speculative risks that had already come into being or that were reasonably projected to occur. At the time of these Defendants' statements, BD was already out of compliance with FDA regulations and the Amended Consent Decree. Indeed, Defendants would later admit and Former Employees corroborate that Alaris was suffering from myriad product defects and BD had for over a five year period made numerous changes to Alaris products ***without*** FDA approval through the 510(k) process. Further, BD failed to establish and/or maintain adequate quality systems related to Alaris, also in violation of FDA regulations. Thus, far from a mere risk that the FDA would, for example, order BD "***to cease manufacturing and distributing products, recall products or take other actions***," Alaris shipments had already been put on-hold following an FDA audit prior to the Class Period, which revealed extensive Alaris product defects (i.e. trackers) that required remediation.

D. December 4, 2019 - Evercore HealthCONx Conference

257. On December 4, 2019, Defendant Reidy attended and spoke on behalf of the Company at the Evercore HealthCONx Conference.

258. During the conference, Evercore ISI analyst, Vijay Muniyappa Kumar, asked Reidy to discuss competition in the pump side (i.e., Alaris) business:

> And switching on to medical, on the med delivery side. I feel like your main competitor on the pump side, they've been, I guess, a little bit more optimistic on what they can do to the market with their new pump launches. Has anything changed at all in the competitive side for you guys on the pump side, Chris?

259. Defendant Reidy replied:

> ***No. Actually, the pump side, we've been taking 200 points of share last year, and we see that continuing, and we have some visibility to that. So we don't see that being the case***.
>
> And I think when you look on the dispensing side, 100 points a share. One of the things that's driving that, that sometimes gets overlooked is our HealthSight middleware that sits over this. ***So we have a lot of connectivity across our product lines there that no other competitor has, and great advantages to that***.

260. Kumar then asked specifically about the timing of Alaris revenue delays: "Just maybe a big picture on medical. I know you had revenue deferral related to the software chain on the pump side, but that's more of a…"

261. Defendant Reidy responded: "***That's a timing issue. First half issue, yes***."

262. Defendant Reidy's and BD's bolded statements identified in paragraphs 259 and 261 were materially false or misleading when made for the reasons set forth in paragraphs 238-40.

E. January 14, 2020 - JPMorgan Healthcare Conference

263. On January 14, 2020, Defendants Reidy and Polen attended and spoke on behalf of the Company at the JPMorgan Healthcare Conference and also provided and presented an investor slide deck entitled "Introducing the Next Phase of Value Creation for BD," which was published on BD's website.

264. At the outset, Polen re-affirmed BD's FY20 Guidance and once more re-assured investors that BD was "very much on track for the full year" FY20 Guidance:

> So before I move on and discuss our capital allocation strategy, let me just pause and make a quick comment on the results for our first quarter. We're off to a really solid start for FY 2020. We just closed our books. And of course, we will provide a complete update in February, but ***I'd say our first quarter is consistent with the guidance we've provided in November, and we remain very much on track for the full year***.

265. Defendants BD, Reidy, and Polen also presented and re-affirmed ***BD's FY20 Guidance*** in the accompanying investor slide deck, as reflected in the below slide:

266. Defendants' bolded statements identified in paragraphs 264-65 were materially false or misleading when made for the reasons set forth in paragraphs 238-41.

267. Robert Justin Marcus, an analyst from JP Morgan Chase & Co, then asked Defendant Polen for an update on Alaris shipments and Defendants' ongoing discussions with the FDA concerning Alaris:

> Another issue from fourth quarter built into guidance for 2020 was in the pump shipments that you are holding off on some of the shipments as you await a guidance from the FDA around fixing some of the alarms. Any update on how that progressed?

268. Defendant Polen declared that BD had: "***Fully resumed shipping in the first quarter. So we're back to shipping in Q1 to the majority of our customers***."

269. When Marcus pressed further, asking "[a]nd so that played out as expected?" Polen responded: "***Exactly as expected***."

270. Defendant's bolded statements identified in paragraphs 268-69 claiming BD's temporary pause on Alaris shipments and discussions with the FDA about purported Alaris software "updates" and "improvements" had played out "exactly as expected" were materially false when made for the reasons set forth in paragraphs 238-39. Moreover, these misrepresentations and omissions gave investors the false impression that FDA oversight and involvement with respect to Alaris software changes had ended with no adverse impact on Alaris revenue or BD's ability to market Alaris products. In truth, Defendants omitted the fact of the FDA's continued active scrutiny of the significant violations, defects, and deficiencies related to Alaris, which had continued for months beginning prior to the Class Period. Indeed, at the time Defendants spoke, BD, in fact, was scrambling to avoid FDA penalties for myriad changes BD had ***already made*** to Alaris ***without*** FDA approval, in clear violation of FDA regulations.

F. January 28, 2020 - Annual Shareholders Meeting

271. On January 28, 2020, the Company held its Annual Shareholders Meeting and provided investors with a presentation entitled "Annual Meeting of Shareholders," which was published on BD's website.

272. During the shareholders' meeting, Defendant Forlenza again represented BD was "on track" to meet FY20 Guidance:

> I'm happy to report that we're off to a really solid start for fiscal year 2020. We look forward to providing you with a complete update on our February 6 earnings call, but ***I'd say that our quarter is consistent with the guidance we provided in November, and we are on track for the full year***.

273. Defendant Forlenza also re-affirmed the Company's ***FY20 Guidance*** in the accompany presentation.

274. Defendant's bolded statements identified in paragraphs 272-73 reaffirming FY20 Guidance and claiming BD was "on track for the full year" were materially false or misleading when made for the reasons set forth in paragraphs 238-41 and 270.

G. February 4, 2020 - BD's "Voluntary" Recall Notification

275. On February 4, 2020, less than two days before the Company's premarket first quarter FY20 earnings call on February 6, 2020, Defendants announced in the February 4 Notification a "voluntary recall" to address specific software issues with Alaris.

276. In that February 4 Notification, Defendants stated that "BD is issuing a ***voluntary recall*** to address specific software issues with the BD Alaris™ System Infusion Pumps" and that "***BD intends to address the issues through an upcoming software release. BD will update the software for affected devices at no charge and will contact affected customers to initiate the scheduling process for the software update when the software becomes available***."

277. Defendants' bolded statements identified in paragraph 276 were materially misleading when made for the reasons set forth in paragraphs 238-39 and because they cast the recall as addressing a minor technical device issue and related fix that would have essentially no impact on the safety or functionality of Alaris products, BD's ability to sell those products, and, thus, BD's financial performance. Indeed, these statements said nothing to suggest that shipments of any Alaris product would be delayed, or that any Alaris product would be unavailable for purchase or sale, shipping or installation, let alone removed from the market, for any period of time while the voluntary recall and software upgrade were implemented. Nor did BD state or indicate that Alaris devices would be unavailable or unsuitable for continued use by customers.

VII. LOSS CAUSATION

278. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class. During the Class Period, Plaintiff and the Class purchased BD common stock at artificially inflated prices and were damaged thereby when the price of BD common stock declined when the truth was revealed.

279. Throughout the Class Period, the price of BD common stock was artificially inflated and/or maintained as a result of Defendants' materially false or misleading statements and omissions. The price of BD common stock significantly declined (causing investors to suffer losses) when Defendants' materially false or misleading statements, alleged herein to have been concealed from the market, and/or the effects thereof, were revealed and/or the risks that had been fraudulently concealed by the Defendants materialized. *See* Section IV.D.5.

280. As a result of the disclosure of the truth of Defendants' fraud, BD's stock price dropped $33.74 (nearly 12%) in one day on unusually heavy trading volume, to close at $252.25 on February 6, 2020.

281. It was entirely foreseeable that Defendants' materially false or misleading statements and omissions discussed herein would artificially inflate and/or maintain the price of BD common stock. It was also foreseeable to Defendants that the revelation of the truth would cause the price of the Company's common stock to fall when the artificial inflation caused or maintained by Defendants' misstatements and omissions was removed. Thus, the stock price decline described above was directly and proximately caused by Defendants' materially false or misleading statements and omissions

VIII. DEFENDANTS FORLENZA AND POLEN ENGAGED IN INSIDER TRADING IN VIOLATION OF SECTION 20A

282. As discussed above, throughout the Class Period, Defendants Forlenza and Polen each were in possession of material, nonpublic information ("MNPI") regarding the Company, including about the nature, extent, and revenue impact of extensive, undisclosed product issues, compliance violations and ongoing scrutiny by the FDA regarding Alaris.

283. Defendants Forlenza and Polen learned these facts and were in possession of such MNPI through, among other ways, their control of BD as the Company's senior executives and participation in or knowledge derived from meetings with the FDA concerning Alaris. Further, Defendants were intensely focused on Alaris, indicating it was a primary driver for FY20 Guidance, and repeatedly spoke to investors about topics specific to Alaris and the FDA. *See*, *e.g.*, Sections V, VI. Indeed, these Defendants are alleged to have made false or misleading statements (*see* Section VI) and Forlenza signed BD's 2019 Form 10-K in which facts were misstated and omitted. *See* Section VI.C.

284. While in possession of the foregoing MNPI concerning BD, Defendants Forlenza and Polen unloaded 146,047 and 6,386 of their personally-held shares of BD common stock, respectively in open market sales, exclusive of sales to the issuer. Forlenza reaped $40,303,346.30 in proceeds from these sales, while Polen took home $1,721,857.18 in proceeds, as reflected here:

Defendant	Total Shares Sold	Proceeds
Forlenza	146,047	$40,303,346.30
Polen	6,386	$1,721,857.18

285. Contemporaneously with Forlenza's and Polen's sales, Plaintiff purchased 23,754 shares of BD common stock at inflated prices, as reflected in the chart below:

Defendants' Insider Sales					Plaintiff Purchases		
Date	**Insider**	**Shares Sold**	**Weighted Avg. Price**	**Proceeds**	**Date**	**Shares Bought**	**Price Per Share**
12/12/2019	Forlenza	11,626	$265.57	$3,087,516.82	12/12/2019	200 200 400	$264.55 $263.38 $264.63
					12/13/2019	900	$268.19
12/16/2019	Polen	1,954 4,432	$269.63 $269.63	$526,857.02 $1,195,000.16	12/16/2019	1,200 200	$269.14 $268.66
					12/17/2019	865	$269.59
					12/18/2019	600	$267.32
					12/19/2019	600	$267.64
					12/20/2019	520	$271.66
1/2/2020	Forlenza	33,365	$271.28	$9,051,257.20	1/6/2020	2,300 695	$273.47 $272.55
					1/7/2020	3,000	$273.10
1/8/2020	Forlenza	13,860	$275.19	$3,814,133.40	1/8/2020	172 2,600 200	$274.79 $273.61 $272.61
1/10/2020	Forlenza	19,675	$275.15	$5,413,576.25	1/13/2020	900	$275.12
					1/14/2020	1,800 272	$274.96 $276.02
1/23/2020	Forlenza	6,284	$280.06	$1,759,897.04	1/23/2020	188 600	$278.99 $278.75
1/24/2020	Forlenza	7,177	$280.13	$2,010,493.01	1/24/2020	200 300 400	$279.54 $278.49 $279.43
1/27/2020	Forlenza	25,546	$280.09	$7,155,179.14	1/27/2020	200 100 600	$276.41 $277.55 $279.90
1/28/2020	Forlenza	28,514	$280.96	$8,011,293.44	1/28/2020	200 1,000	$282.40 $281.66
					1/29/2020	800	$282.40
					1/30/2020	1,300 242	$280.76 $280.73

286. Upon information and belief, thousands of other Class members also purchased shares contemporaneously with the Defendants' sales identified in the table just above. As alleged in this Complaint, at the time of these Defendants' sales and the purchases by Plaintiff and other

Class members, the price of BD's common stock was artificially inflated and/or maintained by the Defendants' material misstatements and omissions.

IX. CLASS ACTION ALLEGATIONS

287. Plaintiff brings this action on its own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all persons and entities who purchased the common stock of BD from November 5, 2019 through and including February 5, 2020, and were damaged thereby. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of BD or any of BD's subsidiaries or affiliates, members of BD's Board of Directors, and members of the immediate families of each of the foregoing (as defined in 17 C.F.R. § 229.404, Instructions (1)(a)(iii) and (1)(b)(ii))); (iii) any of the foregoing individuals' and entities' legal representatives, heirs, successors, or assigns; and (iv) any entity in which any Defendant has a controlling interest.

288. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, BD had more than 270 million shares of common stock outstanding and actively trading on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery and procedure, Plaintiff believes that the proposed Class numbers in the thousands and is geographically widely dispersed. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

289. Plaintiff's claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' alleged conduct in violation of the Exchange

Act as complained of herein. Plaintiff has no interests that are adverse or antagonistic to the interests of other Class members.

290. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in class and securities litigation.

291. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include:

- whether Defendants violated the federal securities laws by their acts and omissions as alleged herein;
- whether Defendants' statements to the investing public during the Class Period misrepresented and/or omitted material facts;
- whether and to what extent the market price of BD's common stock was artificially inflated and/or distorted during the Class Period due to the misrepresentations and/or omissions alleged herein;
- whether Defendants named under Section 10(b) of the Exchange Act acted with the requisite level of scienter;
- whether reliance may be presumed pursuant to the fraud-on-the-market doctrine and/or the *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972) presumption;
- whether the members of the Class have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages; and
- whether the Individual Defendants were controlling persons of the Company.

292. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. THE FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

293. At all relevant times, the market for BD's common stock was efficient for the following reasons, among others:

(i) BD's common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(ii) As a regulated issuer, BD filed periodic public reports with the SEC and the NYSE, in addition to the Company's frequent voluntary public dissemination of information;

(iii) BD regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(iv) BD was followed by multiple securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

294. As a result of the foregoing, the market for BD's common stock promptly digested current information regarding BD from all publicly available sources and reflected such information in the price of BD's stock. Under these circumstances, all purchasers of BD's common stock during the Class Period suffered similar injury through their purchase of BD's stock at artificially inflated prices and a presumption of reliance applies.

295. Further, at all relevant times, Plaintiff and other members of the putative Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Plaintiff and the other members of the Class would not have purchased or otherwise acquired BD common stock at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent that Defendants concealed or improperly

failed to disclose material facts with regard to the Company and its business, Plaintiff and other members of the Class are entitled to a presumption of reliance in accordance with *Affiliated Ute*.

XI. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

296. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

297. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time each statement was made.

298. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

299. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

300. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for any such false or misleading statement because at the time such statement was made, the speaker knew the

statement was false or misleading, or the statement was authorized and approved by an executive officer of BD who knew that such statement was false or misleading.

XII. CAUSES OF ACTION

COUNT I
For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against BD and the Individual Defendants

301. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein. This Count is brought against BD and the Individual Defendants pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, on behalf of Plaintiff and all other members of the Class.

302. During the Class Period, BD and the Individual Defendants, while in possession of material adverse, non-public information, disseminated or approved the false or misleading statements and/or omissions alleged herein, which each defendant knew or recklessly disregarded were false or misleading in that they misrepresented material facts and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Defendants carried out a plan, scheme, and course of conduct that: (i) deceived the investing public, including Plaintiff and other Class members, as alleged herein, regarding the intrinsic value of BD common stock; (ii) caused the price of BD common stock to be artificially inflated and/or maintained artificial inflation in the price of BD common stock; and (iii) caused Plaintiff and other members of the Class to purchase BD common stock at artificially inflated prices that did not reflect their true value. In furtherance of this unlawful scheme, plan, and course of conduct, BD and the Individual Defendants took the actions set forth herein while using the means and instrumentalities of interstate commerce and the facilities of a national securities exchange.

303. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they, individually and in concert, directly and indirectly, knowingly and/or recklessly: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Plaintiff and other members of the Class in connection with their purchases of BD common stock in an effort to maintain artificially high market prices during the Class Period for BD common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5. As alleged herein, the material misrepresentations contained in, or the material facts omitted from, Defendants' public statements included, but were not limited to, materially false or misleading statements and omissions during the Class Period, as alleged here in Section VI.

304. Defendants are liable for all materially false or misleading statements and omissions of material fact alleged above in Section VI. By virtue of their high-level positions at the Company during the Class Period, the Individual Defendants were authorized to make public statements, and made public statements during the Class Period on BD's behalf. The Individual Defendants were privy to and participated in the creation, development, and issuance of the materially false or misleading statements alleged herein, and they and the Company disseminated information to the investing public that they either knew, or were reckless in not knowing, was materially false or misleading.

305. In addition to the duties of full disclosure imposed on Defendants as a result of making affirmative statements and reports to the investing public, Defendants also had a duty to disclose information required to update and/or correct their prior statements, misstatements, and/or omissions, and to update any statements or omissions that had become false or misleading as a

result of intervening events. Further, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including accurate and truthful information with respect to the Company's operations, so that the market price of the Company's common stock would be based on truthful, complete, and accurate information.

306. Defendants' material misrepresentations and/or omissions were made knowingly, recklessly, and without a reasonable basis, for the purpose and effect of concealing from the investing public the relevant truth, and misstating the intrinsic value of BD common stock. By concealing material facts from investors, Defendants maintained artificially inflated prices for BD common stock throughout the Class Period.

307. As a result of the dissemination of the materially false or misleading information and/or failure to disclose material facts, as set forth above, the market price of BD common stock was artificially inflated throughout the Class Period. In ignorance of the fact that market prices of BD common stock were artificially inflated, and relying directly or indirectly on the false or misleading statements made by BD and the Individual Defendants or upon the integrity of the market in which the securities traded, and/or in the absence of material adverse information that was known to or recklessly disregarded by BD and the Individual Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired BD common stock during the Class Period at artificially inflated prices and were damaged thereby.

308. At the time of the material misrepresentations and/or omissions, Plaintiff and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class known the truth underlying Defendants' materially false or misleading statements alleged herein and the intrinsic value of BD common stock, Plaintiff

and the other members of the Class would not have purchased or otherwise acquired BD common stock at the artificially inflated prices that they paid.

309. By virtue of the foregoing, BD and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Class members suffered damages in connection with their purchases and/or acquisitions of BD common stock during the Class Period.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

310. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein. This Count is asserted against the Individual Defendants pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) on behalf of the Plaintiff and all other members of the Class.

311. During the Class Period, each of the Individual Defendants was a controlling person of BD within the meaning of Section 20(a) of the Exchange Act. By reason of their high-level positions at BD and their participation in and/or awareness of the Company's operations and/or intimate knowledge of the materially false or misleading statements and omissions of material fact in statements filed by the Company with the SEC and/or disseminated to the investing public, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company and its executives, including the content and dissemination of the various statements that Plaintiff contends were materially false or misleading.

312. Each of the Individual Defendants exercised day-to-day control over the Company and had the power and authority to cause BD to engage in the wrongful conduct complained of

herein. In this regard, each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be materially misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

313. Each of the Individual Defendants was a direct participant in making, and/or made aware of the circumstances surrounding, the materially false or misleading representations and omissions during the Class Period, as alleged here in Section VI. Accordingly, each Individual Defendant was a culpable participant in the underlying violations of Section 10(b) alleged herein.

314. As set forth above, BD violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of BD and, as a result of their own aforementioned conduct, each of the Individual Defendants is liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as BD is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiff and other members of the Class who purchased or otherwise acquired BD common stock during the Class Period at artificially inflated prices.

315. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases and/or acquisitions of BD common stock during the Class Period.

COUNT III
For Violations of Sections 10(b) and 20A of the Exchange Act and Rule 10b-5 Promulgated Thereunder for Insider Trading
Against Defendants Forlenza and Polen

316. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

317. This Count is asserted for violations of Section 20A of the Exchange Act, 15 U.S.C. § 78t-1(a) on behalf of Plaintiff and all other members of the Class who purchased shares of BD common stock contemporaneously with the sale of BD common stock by Defendants Forlenza and Polen while they were in possession of MNPI as alleged herein.

318. Section 20A(a) of the Exchange Act provides that "[a]ny person who violates any provision of . . . [the Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class."

319. As set forth herein, Forlenza and Polen violated Section 10(b) of the Exchange Act, Rule 10b-5, and Section 20(a) of the Exchange Act for the reasons stated in Counts I and II above. Additionally, Forlenza and Polen further violated Exchange Act Section 10(b), Rule 10b-5, and Rule 10b5-1 (17 C.F.R. § 240.10b5-1) by selling shares of BD common stock while in possession of MNPI concerning the Alaris, as alleged herein, which information they had a duty to disclose, and which they failed to disclose in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged herein. *See* Section VIII.

320. Contemporaneously with Forlenza's insider sales of BD common stock on December 12, 2019, January 2, 2020, January 8, 2020, January 10, 2020, January 23, 2020, January 24, 2020, January 27, 2020, and January 28, 2020, Plaintiff purchased shares of BD common stock on a national securities exchange while Forlenza was in possession of adverse MNPI as alleged herein. ¶ 285.

321. Contemporaneously with Polen's insider sales of BD common stock on December 16, 2019, Plaintiff purchased shares of BD common stock on a national securities exchange while Polen was in possession of MNPI as alleged herein. ¶ 285.

322. Upon information and belief, other Class members purchased shares of BD common stock contemporaneously with Defendant Forlenza's and Polen's insider sales of BD common stock. ¶ 286.

323. Plaintiff and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

324. By reason of the violations of the Exchange Act alleged herein, Defendants Forlenza and Polen are liable to Plaintiff and other members of the Class who purchased shares of BD common stock contemporaneously with Forlenza's and Polen's respective sales of BD common stock during the Class Period.

325. Plaintiff and the other members of the Class who purchased contemporaneously with Forlenza's and/or Polen's respective insider sales of BD securities sales seek disgorgement by Forlenza and Polen, as applicable, of profits gained or losses avoided from Forlenza's and Polen's respective transactions in BD common stock contemporaneous with Plaintiff and other members of the Class.

326. This action was brought within five years after the date of the last transaction that is the subject of Forlenza's or Polen's violation of Section 20A, and, with respect to the underlying violations of Section 10(b) of the Exchange Act alleged in this Count and in Count I above, was brought within five years after the date of the last transaction that violated section 20A of the Exchange Act by Forlenza or Polen.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for judgment as follows:

A. Determining that this action is a proper class action maintained under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

B. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

C. Awarding Plaintiff and the Class compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

D. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

E. Granting such other and further relief as the Court deems just and proper.

XIV. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: August 10, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James E. Cecchi, hereby certify that on August 10, 2020, I caused a true and correct copy of the foregoing Amended Class Action Complaint to be filed electronically with the Clerk of the Court using the ECF system. Notice of this filing will be sent to counsel of record by operation of the Court's electronic filing system. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: August 10, 2020

s/ James E. Cecchi

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